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**'Held together with human glue'
understanding participation in nontherapeutic paediatric randomised controlled trials**

Fisher, Helen

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‘Held together with human glue’: understanding
participation in non-therapeutic paediatric
randomised controlled trials

Kings College London

PhD Thesis

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Helen Fisher

Abstract

Background: Successful recruitment, adherence and retention are essential for randomised controlled trials (RCTs) to produce robust and meaningful findings. Studies exploring trial participation predominantly focus on the characteristics and views of participants and staff and often reveal contradictory findings. To date little is known about adherence and retention to RCTs.

Aim: To further understanding of recruitment, adherence and retention to non-therapeutic paediatric RCTs, with particular emphasis on the role of social context.

Methods: An ethnographic approach was taken using two RCTs as case studies. Participant observation (130 hours) was conducted on a clinical trials unit. Twenty-six trial staff and 56 parents who considered or had participated in the RCTs were interviewed and relevant documents collected. Data were analysed using the principles of thematic analysis.

Results: Drawing on Bourdieu's (1977; 1990) 'Theory of Practice' and Titmuss' (1970) 'The Gift Relationship' it was evident that recruitment, adherence and retention were influenced by the values and beliefs of parents and staff and by the wider context in which the RCTs were conducted. Recruitment and adherence were influenced by the degree of concordance between the philosophies of the trials' fields and those of the wider fields of parenting, infant feeding, medical research and allergy healthcare. Perceptions of personal and societal benefit were relevant to participation but, reflecting the philosophy of the parenting field, families often prioritised personal benefit.

Conclusion: Open and regular personal communication between parents and staff was particularly important for retention. Trials that maximise personal contact may have more success retaining participants. Comparing recruitment, adherence and retention between the two RCTs illuminated the relevance of the wider context for participation, particularly recruitment and adherence. Conducting a thorough assessment of the context in which an RCT will take place will allow potential barriers to participation to be identified before trial commencement.

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This thesis is dedicated to Ralph Fisher

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Chapter 1: Understanding participation in non-therapeutic paediatric RCTs.

Evidence based medicine is a concept that gained momentum in the 1990s following recognition that high quality healthcare relied not on tradition or intuition, but on sound scientific evidence (Rosenberg and Donald 1995; Edwards et al. 1998; Department of Health 2006). Randomised controlled trials (RCTs) are an essential component of evidence based medicine (Sackett et al. 1996; Edwards et al. 1998).

The RCT provides 'gold standard' evidence because the nature of its design minimises bias, thus promoting the reliability and validity of the findings (NICE 2007; Toerien et al. 2009). However, the minimisation of bias is reliant upon the way in which the trial is designed and conducted. For example, bias may be introduced if insufficient participants are recruited (Treweek et al. 2010). After recruitment, problems with adherence, i.e. whether those who take part carry out the trial activities as requested (Robiner 2005) and retention, i.e. whether sufficient numbers of participants remain within the trial until the protocol has been completed (Booker et al. 2011) also challenge the reliability and validity of the findings.

As a paediatric research nurse I was interested in participation in trials. I wondered why parents enrolled their children in research and particularly in why they continued to facilitate their children's participation over a period of some years. I also wondered how trial staff influenced trial participation. An understanding of the influence that recruitment, adherence and retention have on RCT findings and the questions that arose whilst I was conducting trials led to this thesis, in which I aim to further understanding of recruitment, adherence and retention in non-therapeutic paediatric RCTs.

In this introductory chapter I outline the background of the thesis. I begin by elaborating on the use of the RCT in healthcare. I then discuss some of the ethical dilemmas that surround RCTs before exploring the particular challenges faced by those conducting paediatric trials. I go on to consider how these challenges influence recruitment, adherence and retention, explore what is known about recruitment, adherence and retention in paediatric trials and identify gaps in the current knowledge. In the latter part of the chapter I present the aims and objectives of the thesis and briefly outline the methods used in the study.

1.1 The RCT in healthcare

The RCT was designed so that at least two therapies or practices (henceforth referred to as interventions¹) could be compared under controlled ‘experimental’ conditions designed to minimise the potential for bias (Sackett et al. 2000; Treweek and Zwarenstein 2009). A carefully calculated number of individuals (or sample) are randomly assigned to receive one of the interventions under trial or, if no suitable alternative exists (World Medical Association 2008), a placebo. Statistical testing is then used to compare participants’ collective responses between the groups so as to ascertain which intervention, if any, is superior.

RCTs were first used to investigate healthcare practices in the 1930s and 1940s.

Investigators conducted trials to explore the effectiveness of the pertussis vaccine (Chalmers 2010) and to consider whether streptomycin was superior in the treatment of tuberculosis compared with the standard practice of bed rest (MRC 1948). Although the medical community was initially slow to adopt this method of comparing treatments, use of the RCT grew exponentially in the last two decades of the 20th century (Devereaux and

¹ In the definition of an intervention I include standard care, ‘control’ therapies or practices and placebos if they are tested within the context of the RCT.

Yusuf 2003). This reflected a paradigm shift towards evidence based medicine and an understanding that well conducted RCTs are one of the most robust methods of assessing causal relationships (Edwards et al. 1998). It also represented a belief that the scientific advances brought about by research generate commercial opportunity and are thus *'the sources of the new prosperity'* (HM Treasury 2004 p.1).

Although RCTs are now considered an essential tool for informing healthcare practice and policy, there are circumstances under which they are not deemed feasible or appropriate. For example, a case controlled trial showed that supplementing pregnant women's diets with multivitamins reduced neural tube defects in children (Smithells et al. 1980).

However, an ethics committee was reluctant to approve an RCT that aimed to corroborate the findings using a more robust method because of concerns that participants would be deprived of a potentially useful treatment (Sibbald and Roland 1998). Furthermore, in response to concerns that RCT evidence fails to take individual patients' needs into account, some have argued that clinical expertise and patient preference should be used alongside RCT findings to prevent the dehumanization of healthcare (Sackett et al. 1996; Haynes et al. 2002; Rycroft-Malone et al. 2004).

As I will go on to discuss, whilst the RCT has an important role to play in evidence based medicine, some of its most fundamental elements can be both hard to accept ethically and difficult to achieve methodologically.

1.2 Ethical dilemmas associated with RCTs

Ethical concerns began to be raised as soon as the first health related RCT was published in 1948. These worries which, in the opinion of Devereaux and Yusuf (2003), led to reluctance within healthcare to adopt the RCT as a method of scientifically comparing treatments, are still evident in the literature today. The major point of contention is that

individuals who take part in RCTs may be placed at risk of harm to advance researchers' understanding and to improve healthcare, i.e. for societal benefit, but with no guarantee of personal benefit (Edwards et al. 1998; Van Der Graaf and Van Delden 2012).

The acceptability and utility of asking individuals to participate in activities that benefit society but from which they will not personally benefit is a debate that is not unique to research participation. It is also voiced in relation to practices such as blood and organ donation, particularly when considering how to promote participation in these activities (see for example Buyx 2009; Farrugia et al. 2010; Petersen and Lippert-Rausmussen 2011). One of the objectives of this thesis is to contribute to the literature regarding the utility and acceptability of societal versus personal benefit models of participation in research, and I will consider the literature around this debate in greater detail in the following chapter. However, as I go on to describe, the potential for research participants to derive benefit and/or be harmed when taking part in research is frequently discussed with respect to RCT ethics.

1.2.1 Do individuals benefit personally from participation in RCTs?

Whether individuals who participate in RCTs derive benefit from their participation is the matter of some debate. This debate often draws on the distinction between therapeutic and non-therapeutic research (Caldwell et al. 2004; Spriggs 2004) and whilst it is not universally the case, individuals are perhaps more likely to benefit from therapeutic research. For example, participants in an RCT comparing the superiority of two commonly used anti-emetics derive benefit from participation if only because they are receiving treatment for their nausea or vomiting. Conversely, in non-therapeutic research, such as an RCT which aims to establish whether early or delayed introduction of allergenic foods is more effective in preventing children from developing food allergy, the benefits for

those who participate are less obvious. Despite these distinctions, the literature reveals that, regardless of whether RCTs are categorised as therapeutic or non-therapeutic, individuals who take part may benefit in a variety of unintended ways (Edwards et al. 1998). Lantos (1999) referred to this as 'inclusion benefit', and examples of how participants benefit include improved opportunities to access healthcare, closer monitoring of their health, access to the newest medications and contact with professionals who are at the forefront of their field (Edwards et al. 1998).

Regardless of whether individuals benefit from their participation, a concern that is frequently raised within RCT ethics is whether those who take part will suffer harm. This reflects worries about exploitation and experimentation that are common to research more generally, and questions about the acceptability of randomisation, a concern that is specific to randomised trials. These concerns are discussed in the following sections.

1.2.2 Exploitation and experimentation

The history of research reveals many instances in which participants were exploited or harmed under claims of advancing knowledge for society (Day and Ederer 2004).

Examples of such exploitation are provided throughout this chapter, but the experiments that were conducted in the concentration camps by the Nazi Germans during the Second World War had perhaps the greatest influence in shaping the conduct of modern healthcare research. In these experiments individuals were subjected to horrific procedures to help further the knowledge of the ruling government (Shuster 1997). That the researchers were often doctors, who, by membership of their profession had accepted a responsibility not to harm those in their care was particularly concerning (Shuster 1997). Proceedings for war crimes and crimes against humanity were brought against the perpetrators, and from these criminal trials the Nuremberg Code was

developed. This is a set of ten ethical principles that continue to inform practice today by underpinning international guidance and legislation pertaining to research conduct (Rice 2008).

The first principle of the Nuremberg Code states that:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

International Military Tribunals (1950, cited in Shuster 1997)

This principle is reflected in the current requirement, designed to minimise the risk of exploitation, that research participants must provide informed consent prior to participating in research (Department of Health 2005; World Medical Association 2008).

The safeguards brought about by the implementation of the Nuremberg Code and subsequent codes of research conduct such as the Declaration of Helsinki (World Medical Association 2008) and the Research Governance Framework (Department of Health 2005) mean that the harm that previous generations of research participants experienced is uncommon today. Yet instances in which individuals suffer harm as a direct result of their research participation do still happen. In 2006, six of the eight healthy volunteers who took part in a phase I trial of a T cell agonist at a research facility at Northwick Park Hospital experienced life threatening and life changing adverse reactions (Goodyear 2006a). Cases such as these receive significant publicity and provide further support to

those who argue that it is unethical to subject individuals to the risk of harm in the hope of advancing knowledge for society or creating profit for pharmaceutical companies. Others counter this, reasoning that cases where individuals are harmed usually occur because of flaws in the processes of designing, approving or conducting specific RCTs, rather than because RCT participation is risky *per se* (Harris 2005; Goodyear 2006b).

1.2.3 The acceptability of randomisation

The randomisation element of an RCT requires that clinicians allow their patients' treatment to be assigned by chance (Shaw and Chalmers 1970; Hellman and Hellman 1991). This notion contravenes a principle that is accorded substantial value within the sphere of healthcare: that patients should be treated as individuals and prescribed therapies that, after taking their specific condition and needs into account, are deemed to be in their best interests (Chartered Society of Physiotherapists 2005; College of Occupational Therapists 2005; General Medical Council 2006; Nursing and Midwifery Council 2008). Perhaps for this reason some clinicians find it particularly hard to put aside their personal knowledge and beliefs about which intervention is best for their patient and accept that those who participate in RCTs will be randomly assigned to one of the interventions under trial.

The concept of equipoise was introduced to help overcome this dilemma and proposes that RCTs may only be conducted when there is uncertainty within the healthcare community regarding the equivalence of the interventions being tested (Freedman 1987). Equipoise promotes an ethical approach to RCTs because this uncertainty means that clinicians cannot say which intervention is superior; thus randomisation becomes acceptable. Although there are calls to for the concept to be better defined (van der Graaf and van Delden 2011) or abandoned in favour of a risk-benefit assessment (Joffe

and Miller 2012) or non-exploitation framework (Miller and Brody 2007), equipoise currently remains one of the key ethical underpinnings of the RCT (Garcia et al. 2004; Miller and Brody 2007).

Whilst exploitation, experimentation and randomisation have been cited as reasons that RCTs should not be conducted, a contrary argument also exists: that it is unethical not to carry out RCTs (Spriggs 2004; Shirkey [1968] 1999). In the following section I expand upon this argument, which whilst applicable to all realms of healthcare, is particularly evident in the literature regarding children's research participation.

1.3 Inclusion of children in research

Meaux and Bell (2001) argue that the history of children's inclusion in research reflects society's changing views of childhood. They describe how, in the early eighteenth century when children were viewed as 'property,' experimentation was generally deemed acceptable. However, the industrial revolution marked a change in the place that children occupied in society, and the value that they held as part of the workforce led to increased worries about their health.

As children came to be seen as a valuable part of society their rights also improved. Recognition that research was being conducted without the knowledge or consent of children or their parents, and that the procedures that children were subjected to were frequently risky, painful and unnecessary, led to concerns about exploitation and coercion (Lederer 2003). A particularly poignant example of this was research that was conducted on children with learning difficulties who attended Willowbrook School in New York in the 1950s, 60s and 70s. These children were deliberately infected with hepatitis so that researchers could investigate vaccine efficacy. Although parents were aware that their children were taking part in research there was a sense of unease that they had been

coerced into providing consent with promises of expediting the time spent on the waiting list to attend the school (Friedman Ross 2006; Jonsen 2006). Concerns about the infringement of the rights of the children who participated in other trials led journal editors to reject papers that reported their findings (Lederer 2003). For these reasons, in the early part of the twentieth century, paediatric research was not commonplace. Towards the latter part of that century the situation began to change.

1.3.1 Changes affecting the inclusion of children in research

In the late 1960s Harold Shirkey outlined the ramifications of failing to include children in medical research. In an editorial published in the journal *Pediatrics*, he highlighted the number of medications deemed unsuitable for children, not because of any known adverse effects, but because they had not been tested for use in the paediatric population (Shirkey [1968] 1999). Whilst adults were enjoying the benefits of therapies that were known to be safe and effective following rigorous testing in RCTs, differences in physiology, pathophysiology and pharmacokinetics meant that these results were not directly applicable to the paediatric population. Due to a lack of paediatric research children were either denied medication that had been shown to be useful in adults, or were put at risk by being prescribed medication for which efficacy and safety in the paediatric population was unknown (Wilson 1999; Shirkey [1968] 1999).

The crux of Shirkey's editorial reflects the counter argument to those who question whether it is acceptable to ask individuals to participate in activities from which they may not derive benefit and may be placed at risk of harm to benefit others. He essentially argued that the failure to include children in research meant that, each time an untested therapy was prescribed, children were taking part in 'natural' experiments (Shirkey [1968] 1999). As Kipnis (2003) highlights, the desire to protect children extended too far, and

these natural experiments both could and did result in substantial numbers of children experiencing harm (Cote et al. 1996). For example, neonates were routinely treated with high levels of oxygen until an RCT identified the practice as a risk factor for retinopathy (Sibbald and Roland 1998). When contrasted with examples of the beneficial effects of research programmes, such as the rise from 25% to 70% in the five year survival rate of children with leukaemia (Caldwell et al. 2004), the potential value of RCTs is apparent, even in groups for whom the ethical challenges are magnified.

Shirkey ([1968] 1999) first highlighted the ramifications of failing to conduct paediatric research and labelled children as ‘therapeutic orphans’ in 1968. However, it was not until the late 1990s that the need to redress the dearth of evidence based care for children was officially recognised by legislation introduced in the USA (National Institutes of Health 1998) and, eight years later, Europe (European Parliament 2006). Various reasons may exist for this delay. As childhood conditions often affect relatively small numbers of children, the development of therapies for these orphan diseases (Wilson 1999) offered governments and industry little potential for financial reward; thus research into childhood conditions was not viewed as financially worthwhile (Wilson 1999; Caldwell et al. 2004).

An additional reason that healthcare was slow to adopt the RCT in the field of paediatrics reflects challenges with the provision of consent (Westra et al. 2010). Depending on their age and stage of development, children may not have sufficient understanding of research to provide informed consent, a critical ethical requirement (Department of Health 2005; World Medical Association 2008). To counter this problem parents or legal guardians must provide consent on behalf of children who are younger than 16 years of age, although the views of the child should be obtained and taken into account (Royal

College of Paediatrics and Child Health: Ethics Advisory Committee 2000). Yet questions have been raised about whether this 'proxy' consent is as valid as the consent provided by an adult for their own trial participation. Although Harris and Holm (2003) point out that parents can and do make decisions on behalf of children every day, others highlight that parents do not always find it easy to understand what trial participation involves and consider making research decisions on behalf of their children is difficult (Kodish 2003; Allmark and Mason 2006a).

The problem of proxy consent has been debated in the law courts. In the case of *Grimes v Kennedy Krieger Institute*² two parents sued the Institute for negligence after their children developed health problems following lead exposure during participation in a trial exploring lead reduction measures in the home. There were several procedural problems with the RCT, particularly regarding whether the trial should have received ethical approval to be conducted (Mastroianni and Kahn 2002; Spriggs 2004). However, the judge concluded that parents could not consent to their child's participation in non-therapeutic research from which they were unlikely to benefit if there was any risk of harm. Although this ruling was later overturned (Spriggs 2004), it highlights the magnitude of concern regarding the enrolment of children in research, where worries about informed consent and risk of harm limited the number of paediatric RCTs that were conducted.

Despite the challenges faced by those who conduct RCTs with children, changes in legislation mean that the number of paediatric RCTs being conducted is increasing (Fern et al. 2008; Pandolfini et al. 2009) and thus a greater proportion of the care that children receive should be evidence based. However, the utility of such evidence will depend upon

² *Grimes v Kennedy Krieger Institute Inc* 366 Md 29. 782 A2d 807 (2001)
http://biotech.law.lsu.edu/cases/research/grimes_v_KKI.htm (accessed 15/05/2012)

its quality. As I go on to discuss, the quality of RCT evidence can be compromised by methodological challenges during trial design and conduct.

1.4 Challenges to the quality of evidence produced by RCTs

When well conducted in the correct situations, the RCT is an effective method of developing robust evidence to inform practice (NICE 2007). However, the robustness of the evidence may be reduced by a variety of methodological problems which introduce bias, the very flaw that the RCT is designed to minimise (Prescott et al. 1999; Treweek and Zwarenstein 2009). Bias may occur during either the design or the conduct phases of an RCT. During the design phase incorrect sample size calculations and poor choice of data collection tools and methods threaten the validity and reliability of RCT findings. Three key areas which have the potential to introduce substantial bias in the conduct phase are: the failure to recruit sufficient participants or bias in the types of participants that are recruited; poor adherence to trial activities; and high numbers of participants withdrawing from the trial before all the necessary data are collected (Campbell et al. 1998; Prescott et al. 1999; Devereaux and Yusuf 2003; McDonald et al. 2006). The way in which bias can be introduced within these three aspects of participation is discussed in the following sections.

1.4.1 Recruitment

In well-designed RCTs the number of participants is calculated to ensure that the statistical significance of differences between group responses to the interventions can be assessed. Problems recruiting sufficient participants are not uncommon (Donovan et al. 2003; Toerien et al. 2009; Shilling et al. 2011) although publication bias makes it difficult to estimate the number of RCTs that fail to recruit an adequate sample (Prescott et al. 1999). However, in a review of RCTs that were funded by the Medical Research

Council or Health Technology Assessment programme, McDonald et al. (2006) found that only 31% met their recruitment targets and just over half (53%) were awarded extensions to their recruitment periods. These findings highlight that, even when funded by prestigious organisations, around a third of RCTs do not recruit the required number of participants. Damen et al. (2012) found similar results when examining recruitment to 107 RCTs that had been approved by a local ethics committee. Thirty eight percent failed to recruit sufficient participants and investigator initiated trials were statistically more likely to have problems than trials run by pharmaceutical companies.

Problems with recruitment have several ramifications. Trials that cannot recruit participants are often discontinued early and thus fail to produce meaningful findings (McDonald et al. 2006; Davidson et al. 2010). RCTs in which researchers struggle to recruit sufficient participants may be prolonged beyond the expected duration, incurring additional costs (Prescott et al. 1999; McDonald et al. 2006). Even when the required numbers of participants are recruited, if the included participants are not representative of the population to which the research applies, for example if a particular gender, age group or ethnicity is over or underrepresented, the practical utility of trial findings is likely to be limited (Bain 2001).

1.4.2 Adherence

As RCTs are designed to test specific interventions under controlled conditions, participants are asked to carry out activities according to a regime designed to maximise the potential that statistical testing will reveal differences between the groups. Ensuring that trial participants carry out the activities that the protocol requires has often been referred to as compliance. Recently, in a bid to overcome the paternalistic connotations that the term compliance conjures, the practice is more commonly referred to as

adherence (Robiner 2005). Differences in reporting methods make it difficult to assess the number of trials where the findings are influenced by poor adherence. Although the literature carries evidence of a range of diligence in adherence to trial activities, reports of poor adherence to RCTs are not uncommon (see for example Lasagna and Hutt 1991; Epstein 1996; Lawton et al. 2011).

The extent to which participants adhere to RCT requirements has several implications. If large numbers of participants fail to adhere then the statistical power to detect differences between the interventions is likely to be reduced. This will result either in an inability to detect differences that would otherwise exist, or in an increase in trial costs due to an increase in the sample size needed (Shumaker et al. 2000; Robiner 2005). Poor adherence may result in '*erroneous conclusions*' (Robiner 2005 p.66) regarding the effectiveness of the interventions under trial. As Ickovics and Meisler (1997) explain, if individuals fail to adhere to a treatment regime because of unpleasant or intolerable side effects then the safety of the treatment may not be adequately determined; if they fail to adhere because they consider the treatment is not working the effectiveness of the therapy may be over or underestimated.

Whilst the methodological quality of a trial is clearly influenced by adherence, Treweek and Zwarenstein (2009) argue that trials which include only data from participants who are fully adherent are, in themselves, biased: in everyday life patients rarely follow their treatment regimes as precisely as if they were in a '*laboratory environment*' (p.38). This may be overcome by conducting an 'intention to treat analysis' in which participant data are analysed according to the group to which they were allocated and regardless of adherence. Furthermore an increasing number of 'pragmatic' trials are being conducted in which investigators aim to assess whether an intervention is effective in 'real world'

conditions. In such trials variable adherence to the intervention is seen as acceptable and useful information for assessing an intervention's utility in daily practice (Roland and Torgerson 1998; Godwin et al. 2003).

1.4.3 Retention

One of the conditions of trial participation is that individuals are free to withdraw at any time without giving a reason and there is an acceptance that not all participants who enrol onto an RCT will remain until the trial ends. To counter the effects of the loss of data that results when participants withdraw early, sample sizes are calculated to allow some participants to withdraw (Fewtrell et al. 2008). However, if more participants withdraw than are allowed for in these calculations then the findings may be underpowered to detect any effect. This would result in an inaccurate assessment of the effectiveness of the intervention. It is difficult to estimate the number of RCTs affected by poor retention. Many such trials go unreported and accounts of withdrawals in published trials can be hard to interpret due to variability in reporting methods (Toerien et al. 2009). However the problem is likely to be significant (Brueton et al. 2011).

Poor retention has similar ramifications for the validity of RCT findings to poor recruitment. If large numbers of participants fail to complete the trial protocol the findings will, at best, be biased due to an unrepresentative sample and, at worst, will fail to reach statistical power and thus to answer the question that was posed (Robinson et al. 2007; Toerien et al. 2009; Brueton et al. 2011).

1.4.4 Summary

RCTs which produce poor quality findings not only hamper the advancement of evidence based knowledge, they also have financial and ethical consequences. In a time of limited finances, expenditure on trials that fail to achieve meaningful results is wasteful;

resources expended on such trials could have been better employed elsewhere (Morse et al. 1995; Prinz et al. 2001). Furthermore, individuals who participate in trials that fail to produce meaningful results will have been exposed to unnecessary procedures. This is considered to be ethically unacceptable (World Medical Association 2008).

Problems with recruitment, adherence and retention may occur in all RCTs regardless of the age group of the participants but, for the reasons described earlier, paediatric RCTs present particular challenges. A desire to understand and overcome these challenges has resulted in a body of work that explores the barriers and facilitators of participation in paediatric RCTs. A review of this literature, focusing particularly on how parents and practitioners influence recruitment, adherence and retention,³ was undertaken. SCOPUS and Cochrane online databases were searched using the terms that are presented in Appendix 1. All articles that explored recruitment, adherence or retention in paediatric RCTs and that were written in the English language were suitable for inclusion in the review. Titles and abstracts of returned articles were scrutinised and full text articles obtained for papers likely to be relevant to recruitment, adherence and retention. Reference lists of retrieved articles and review papers were also searched for relevant studies, and experts were asked to recommend suitable papers. The majority of the identified literature relates to recruitment, although a small number of studies have considered the factors that influence adherence and retention in paediatric trials. The literature is discussed in the following sections.

³ Although children also influence participate in research, given that parents must usually provide the final consent for their child's participation and, depending on their age, facilitate their ongoing participation, they were not the focus of the review.

1.5 Recruitment to paediatric RCTs

A growing number of studies have examined the factors that influence recruitment to paediatric RCTs and their findings are summarised in the following sections. The majority of the literature considers parental willingness to consent to their child's participation in an RCT or considers whether sociodemographic factors can help to predict parents who are more or less likely to consent to their child's participation. A small number of studies have considered whether researcher or trial specific factors are relevant.

1.5.1 Research as an opportunity for personal or societal benefit

Parents consent to their child's participation because they view RCTs as an opportunity to help their child or family (Liaschenko and Underwood 2001; Pletsch and Stevens 2001b; Taylor and Kass 2001). This opportunity manifests as the potential to access the newest medications (Clausen et al. 1954; Deatrick et al. 2002; Rothmier et al. 2003; Chantler et al. 2007; Schaffer et al. 2009), the chance to access free healthcare (Fairhead et al. 2006; Masiye et al. 2008) and a more convenient way to access standard healthcare (Glogowska et al. 2001; Chantler et al. 2007; Jay et al. 2007).

The potential to benefit society also motivates parents to enrol their children in RCTs (Langley et al. 1998; van Stuijvenberg et al. 1998; Deatrick et al. 2002; Hoehn et al. 2005; Sammons et al. 2007; Ward 2009). This is discussed in relation to parental belief that contributing to science is important (Rothmier et al. 2003; Chantler et al. 2007) and in terms of a perceived obligation to repay previous families who participated in research, the findings of which have benefitted their children (Jollye 2009; Woodgate and Yanofsky 2010).

Whilst the literature suggests that societal and personal benefit both influence recruitment to paediatric RCTs, the emphasis placed on more altruistic motivations seems

to be context dependent. In the studies included in this review, more parents with healthy children cited altruistic motivations as their primary reason for participation than parents whose children had a life threatening or life limiting illness. The literature regarding personal and societal benefit is discussed in greater detail in the following chapter.

1.5.2 Risk, harm and trust

Perception of risk is clearly important to recruitment to paediatric RCTs. Parents cite safety as their first concern when deciding whether to enrol their children in an RCT (Pletsch and Stevens 2001a; Chantler et al. 2007; Shilling et al. 2011) and impose stricter criteria for agreeing to research participation for their children than for themselves (Pletsch and Stevens 2001a; Chantler et al. 2007). Fear of experimentation and the unknown risks of RCT participation negatively influence recruitment (Mazzocco et al. 1999; Burgess et al. 2003; Hoehn et al. 2005; Snowden et al. 2007; Jollye 2009).

Whilst Tait et al. (2003) found that low perceived risk was a good predictor of consent to research, it appears that perception of risk is highly personal. In an interview study of 34 mothers who considered enrolling their young children in vaccine research, parents cited the risks of participation as both reason to take part and reason not to (Chantler et al. 2007). When considering differences between the parents, Chantler et al. (2007) found that those with medical or scientific backgrounds were less concerned about the risks of participation. They hypothesised that familiarity with research may have improved trust in the researchers, a concept that others report as important for parents considering enrolling their children in trials (Taylor and Kass 2001; Kaljee et al. 2007; Helgesson et al. 2009; Swartling et al. 2009; Woodgate and Yanofsky 2010; Gamble et al. 2012). Tait et al.

(2004) found that trust in the medical system and research influences recruitment by improving parental assessment of the risks of participation.

Parents weigh the risks against the benefits when deciding whether or not to enrol their children in research (Pletsch and Stevens 2001a; Deatrick et al. 2002; Oppenheim et al. 2005; Dunngalvin et al. 2009). Parental risk benefit assessments seem to be influenced by the health of the child. Dunngalvin et al. (2009) analysed the reasons that parents accepted or declined an invitation to enrol their children in a trial of oral immunotherapy for food allergy. They found that parents who chose to take part considered their children to be more at risk of suffering an allergic reaction in their daily lives and were more concerned that this reaction would be fatal than those who declined the invitation. A narrative synthesis of qualitative studies similarly revealed that parents with very sick children place less emphasis on the risks of a trial and perceive the potential for benefit to be greater than parents with healthier children (Fisher et al. 2011).

Parents' opinions of risk also relate to the way a trial is presented. Tait et al. (2010) found that pictographs helped parents to understand risk benefit information better than text or tables. Cico et al. (2011) asked parents attending the accident and emergency department to rate their willingness to enrol their children in hypothetical research which was described using the terms 'research project,' 'research study,' 'medical experiment,' and 'medical study'. They found that 63% of parents rated the terms as having different levels of risk, safety and inclusion of untested treatments. These ratings influenced their willingness to agree to their child's participation in the research. Parents rated 'research study' as the safest and were more willing to allow their children to participate in such a study than those described using one of the other phrases. They considered the 'medical experiment' was most likely to involve a novel treatment, procedure or medicine and

offered the greatest risk. Given the relationship between risk and parental willingness to consent to their children's participation that others have found, it is perhaps unsurprising that few said they would agree to their child taking part in the study when the phrase 'medical experiment' was used. Whilst these findings are interesting, the hypothetical nature of the study may have influenced parents' answers.

1.5.3 Trial design

Various aspects of trial design appear relevant to recruitment to paediatric RCTs. Dislike of randomisation and parental preference for an intervention presents challenges for recruitment (Canvin and Jacoby 2006; Sammons et al. 2007). Although parents interviewed by Jollye (2009) did consent to their child's participation despite having a preference for one particular group, they said they would have withdrawn if their child were randomised to the alternative group.

Parental concern about subjecting children to painful procedures is also important (Pletsch and Stevens 2001a; Burgess et al. 2003; Helgesson et al. 2009; Read et al. 2009), and trials involving venepuncture may have particular difficulty recruiting children (Jay et al. 2007; Lernmark et al. 2011). Gattuso et al. (2006) found that studies involving blood collection in paediatric cancer trials had twice the rates of refusal than those that did not. Parents consider the character of their child when considering whether they will manage to cope with such activities (Chantler et al. 2007; Woodgate and Yanofsky 2010) and take the child's own views into account (Pletsch and Stevens 2001b; Deatrack et al. 2002; Shilling et al. 2011) before agreeing to participation.

Perceptions of the burden of research participation (e.g. frequency of visits to the hospital) are important to parental willingness enrol their children in RCTs; trials where the burden is considered minimal have fewer problems recruiting participants (van

Stuijvenberg et al. 1998; PENTA 1999; Taylor and Kass 2001; Gattuso et al. 2006; Jay et al. 2007; Read et al. 2009; Lernmark et al. 2011). Some parents agree to research participation because they feel it will make their lives easier through the provision of standard healthcare at a more convenient time or place (Chantler et al. 2007; Masiye et al. 2008), although the retrospective nature of the data collection methods used by these studies may have influenced this finding.

1.5.4 The invitation to participate

The way that parents are invited to enrol their children in research is important for successful recruitment. Recruitment may be hampered by clinicians' reluctance to discuss potential participation with families for fear of overburdening them (Snowdon et al. 2004; Chamberlain et al. 2009; Shilling et al. 2011). Whether clinicians have time to fit recruitment to trials around their clinical commitments is also important (Caldwell et al. 2002; Chamberlain et al. 2009).

Although several studies have found that clinicians may be concerned about inviting parents to enrol their children in research, others reveal that these concerns are unfounded; parents do not usually mind receiving such an invitation (Shilling et al. 2011; Ward 2011). However, whilst parents are happy to receive an invitation and mostly want to make participation decisions themselves (Zupancic et al. 1997; Burgess et al. 2003), they may be swayed by the opinion of those who extend the invitation. Snowdon et al. (2004) found that clinicians' perceptions and knowledge of research, and the manner in which they presented the study were relevant to parental willingness to allow their child to undergo a post mortem for research purposes. Some parents felt that the clinician discussed the research with them in a way that guided them away from consenting.

Others have also found that the way that clinicians view a trial may result in biases in recruitment. Amiel et al. (2007) found that some clinicians did not invite eligible families to take part in research due to concerns about the ethical underpinning of the trial, whilst others extended the invitation to those they thought most likely to agree to participate, a finding that has implications for the representativeness of the sample and thus trial findings.

Australian paediatricians interviewed by Caldwell et al. (2002) held similar views to those interviewed by Amiel et al. (2007) regarding the ethics of RCTs. Clinicians' dislike of randomisation and lack of personal equipoise were likely to have influenced parents' decisions about enrolling their children in research. Paediatricians suggested that rivalry between differing research groups and competition to enrol children into trials was also relevant to whether they informed families about relevant trials. Furthermore, recruitment was influenced by paediatricians' concerns about whether the invitation to participate in research, particularly discussions of uncertainty regarding the correct treatment, would influence the doctor-patient relationship (Caldwell et al. 2002).

Adopting a direct or indirect approach to inviting parents to enrol their children in research is also relevant to recruitment. Direct approaches have been found to be more effective (Mazzocco et al. 1999; Raynor et al. 2009) but may have ethical connotations. In an ethnographic study Fairhead et al. (2006) considered that some recruiters had distorted the truth regarding participation by emphasising the benefits of taking part whilst limiting discussions about the risks of participation. This approach resulted in few parents refusing to participate, but did not uphold the principles of informed consent.

The timing of the invitation has a role to play in recruitment with regards both to parents' personal circumstances and to the way the topic is viewed in society. Parents who were

invited to enrol their children in research soon after receiving the news that their child had a life threatening condition described feeling overwhelmed (Jollye 2009; Ward 2009) and confused and pressurised to make a decision (Levi et al. 2000). Woodgate and Yanofsky (2010) found that parents passively accepted an invitation to enrol their child in an RCT soon after receiving news that their child had cancer. However, in their study of electroencephalogram (EEG) of healthy neonates Korotchikova et al. (2011) found that mothers who were invited to participate more than six hours after delivery were almost twice as likely to take part as those invited less than six hours after giving birth. These findings provide further evidence that the health of the child and parents' perceptions of the potential for benefit are likely to be relevant to recruitment. They also suggest that parents' state of mind and thus ability to contemplate participation are important for recruitment. This is substantiated by Harth et al. (1992) who found that parents who agreed to enrol their children in an RCT of a new asthma drug had lower self esteem, were more introverted and exhibited greater anxiety than those who chose not to take part. They cautioned that parents who volunteer their children for research may be more emotionally vulnerable than those who do not.

How the topic is viewed in society also influences parental willingness to consent to their child's trial participation. Negative publicity regarding vaccines hampered recruitment in vaccine trials that were conducted in the 1950s and the early part of the 21st century (Clausen et al. 1954; Chantler et al. 2007). However, negative publicity about the topic of research does not always have a negative effect. Parents who took part in a study exploring the way that families discussed sex education with their teenagers said that they were encouraged to take part after seeing media coverage of Britain's youngest mother, who was expecting her first child at 12 years of age (Lewis 2009).

1.5.5 Sociodemographic characteristics

Several studies have explored whether sociodemographic characteristics are relevant to recruitment. As early as the 1950s demographic influences were noted to play a role in recruitment when Clausen et al. (1954) discovered mothers who agreed to their children participating in vaccine research had a higher educational level than those who declined participation. Since this time, despite several studies considering this issue, whether sociodemographic factors are relevant to recruitment remains unclear. Conflicting results are evident in studies exploring the influence of parental educational level (Harth and Thong 1990; Tait et al. 2003; Kaljee et al. 2007) and ethnicity (Gattuso et al. 2006; Liese et al. 2008; Read et al. 2009). Sex of the child (Gattuso et al. 2006; Kaljee et al. 2007; Dunngalvin et al. 2009), age of the child (Kaljee et al. 2007; Dunngalvin et al. 2009), household income (Kaljee et al. 2007), and maternal age, marital status or nationality (Korotchikova et al. 2011) do not appear to influence recruitment to paediatric RCTs. These findings suggest that contextual factors may have a greater influence on recruitment than sociodemographic factors.

1.5.6 Limitations of the literature regarding recruitment to paediatric RCTs

The current literature has some limitations. Many studies exploring recruitment to RCTs have used questionnaires, a design that limits understanding of the factors that those who are directly involved find important. Few studies have explored factors that are beyond the sociodemographic characteristics of families or parental perceptions of RCTs, although papers included in this review provide some evidence that trial staff, trial design, and the way that the intervention under trial is viewed by society exert an influence on recruitment.

The majority of studies have considered the factors that influence recruitment in either therapeutic trials or in non-therapeutic trials of highly novel medications (e.g. phase 1

oncology RCTs). Spriggs (2004) considers the therapeutic/non therapeutic distinction to be unhelpful, particularly with regards to risk versus benefit assessments of RCTs, because these judgements should reflect whether risks are acceptable *per se* rather than whether they are acceptable in relation to potential benefits. However, given the emphasis parents and clinicians (Estlin et al. 2000) place on the benefits of participation, it would be useful to understand whether different issues are relevant for therapeutic trials than is the case in non-therapeutic RCTs, particularly those that do not involve the testing of drugs or vaccines. Furthermore, although the level of detail provided in the published studies means that it is not always possible to determine the nature of the RCTs, it seems that, with the exception of Phase 1 trials in oncology, few studies appear to have considered the factors that influence recruitment in 'proof of concept' trials.⁴ Consequently is hard to say how the novel nature of such studies might influence parents' and clinicians' views of such trials.

1.6 Adherence in paediatric RCTs

Despite the importance of adherence to research procedures for trial outcomes and an acceptance that adherence to medications and interventions in healthcare may be poor (Bender 2002; De Civita and Dobkin 2005; Wrubel et al. 2005; Ingerski et al. 2009), few studies have explored the factors that influence adherence in paediatric RCTs.

There is some evidence that sociodemographic factors are relevant to adherence to trial activities. Younger maternal age and lower level of parental education has been associated with lower adherence (Janus and Goldberg 1997; Mahrshahi et al. 2008), whilst

⁴ Proof of concept trials test the effectiveness and safety of novel interventions, whilst trials of equivalence test the relative merits of commonly used therapies that have been proven to be safe and effective in previous trials.

non-white mothers were less likely to be adherent to RCT interventions in a trial of allergy prevention measures (Mihirshahi et al. 2008).

The health status of the participating child has also been shown to influence adherence, although the direction of the relationship is not clear. Bender et al. (2003) found that healthier children and those with milder disease were more likely to miss visits in their double blind placebo controlled (DBPC) trial of inhaled treatments for children with mild-moderate asthma. Conversely Roder et al. (2008) found that children who were less adherent in an RCT of sublingual immunotherapy for hay fever had worse symptom scores before the trial than those who were more adherent. Although this finding may reflect the health status of the child, it may also be an indication of adherence behaviour. Children who were less adherent during the trial may also have been less adherent to their medications before commencing the trial and thus have had worse symptom scores.

Levels of adherence in longitudinal trials have been shown to reduce over the duration of an RCT (Johnson et al. 2007; Johnson et al. 2009; Thornburg et al. 2010) although alterations to the regime may lead to periods of improved adherence. In their longitudinal double blind placebo controlled RCT of hydroxyurea for infants with sickle cell anaemia or thalassaemia, Thornburg et al. (2010) found that, when medication doses were titrated according to the child's medical condition, parents were more adherent to the trial regime than when children had been on a stable dose of medication for a sustained period of time.

1.6.1 Limitations of the literature regarding adherence to paediatric RCTs

The literature exploring adherence in paediatric RCTs is limited and predominantly uses analysis of secondary data considering the sociodemographic characteristics of parents, health of the children and the effect of time. No study has sought to understand the

aspects of adherence that are relevant to parents, although studies exploring adherence to medications that are prescribed for health conditions suggest that age of the child, palatability of the medication and interference with daily life are relevant (see for example Goode et al. 2003; Lawrence et al. 2008; Simons et al. 2009).

Adherence to medical regimes has been the subject of substantial research and is dependent on a variety of factors, including the complexity of the medication regime (Claxton et al. 2001), the relationship between healthcare professionals (HCPs) and patients (Horne et al. 2005), and the patients' daily routines and practices (Rosenfeld and Weinberg 2012). Reviews exploring the efficacy of interventions aimed at improving adherence reveal inconsistencies: interventions shown to work in certain scenarios are ineffective in other situations (van Dulmen et al. 2007; Haynes et al. 2008).

Although there is a considerable body of knowledge about adhering to medical regimes (see for example, Horne et al. 2005; Rueda et al. 2006; Haynes et al. 2008; Dean et al. 2010), it is not possible to apply these findings directly to the research context.

Adherence to research protocols is likely to be complicated both by participants' original motivations for participation and by the additional activities that are involved in taking part in a trial. Furthermore, no paediatric studies have explored the role of the researcher on adherence. However, in a study of the reasons why few participants met the target HbA(1c) level in an RCT exploring treatments for adult diabetes, Lawton et al. (2011) found that trial staff tailored the protocol to meet the needs of their patients and thus had a substantial influence on adherence within the trial.

Most of the empirical studies have been conducted in relation to therapeutic trials. Yet participants in non-therapeutic trials, for whom participation is unlikely to have any direct health benefit, may well hold different views about adherence than those who participate

in therapeutic trials, for whom adherence to the intervention has the potential to directly improve their health. It is thus necessary to investigate adherence practices in such trials.

1.7 Retention in paediatric RCTs

Failure to retain adequate numbers of children in an RCT has similar ramifications for the methodological quality of the trial's findings as failure to recruit sufficient participants.

Yet it is interesting to note that, whilst researchers are increasingly concerned with understanding what influences recruitment to RCTs, far fewer have considered the factors that are relevant to retention.

Three studies have considered whether sociodemographic factors influenced retention.

Williams et al. (2008) found that parents who withdrew their children from a longitudinal study of HIV therapy were less well educated than those who completed the study.

Conversely Allehoff et al. (1988) found that parents with higher educational levels were more likely to withdraw their children from a longitudinal trial in the field of child psychology. However, Geromanos et al. (2004) found that sociodemographic status had no influence on completion of a study of children born to HIV infected women. These conflicting results suggest that context may be more important than sociodemographic factors for trial retention.

Trial specific factors have been shown to be important to trial retention. Raynor et al. (2009) found that families who were recruited to RCTs targeting childhood obesity via indirect methods had higher rates of retention than those recruited by their physicians.

This suggests that differences in participants' motivations for participation may be relevant to retention. In their review of the factors that influenced retention to a multicentre RCT of HIV treatment, Williams et al. (2008) concluded that smaller sites, particularly those without a study coordinator, had the lowest rates of retention.

Moreover, sites that did not offer financial incentives had lower rates of retention than those that did, suggesting that personal benefit may be relevant to retention as well as recruitment.

The health of the participating child has also been found to be relevant to retention although the literature is conflicting. Three studies (Janus and Goldberg 1997; Bender et al. 2003; Williams et al. 2008) found that children with milder disease states were more likely to withdraw or be lost to follow up than those with more severe disease processes. That parents in two studies cited access to healthcare as reason to remain in a trial (Geromanos et al. 2004; Dias et al. 2005) suggests that parental perception that continuing participation is beneficial to their child positively influences trial retention. Yet other studies reveal conflicting results. Children with the worst quality of life scores at the beginning of an RCT of diabetes therapies were the most likely to withdraw (Driscoll et al. 2009) and Hoste et al. (2007) also found that those who had suffered from an eating disorder for a long time were more likely to drop out of trials of therapies for the condition. This discrepancy suggests that contextual factors are likely to be relevant to retention. Certainly parental satisfaction with the care their children received and ease of participation seems to have a positive influence on retention (Pletsch and Stevens 2001a; Roder et al. 2008). Parental views of the researchers are also important. Perez et al. (2010) found that those who withdrew their children were less positive about their interactions with researchers than those who completed gastroenterological RCTs.

1.7.1 Limitations in the literature regarding retention in paediatric RCTs

The literature provides only a limited understanding of what may influence retention in paediatric RCTs. Whilst sociodemographic factors and the health of the participating child may be important the literature reveals conflicting results suggesting that contextual

factors are also likely to be relevant. Furthermore, all studies exploring retention in paediatric RCTs used secondary analysis of data or questionnaires, designs that do not allow a detailed consideration of the issues that are pertinent to parents or trial staff. As yet, therefore, the factors that influence retention to paediatric RCTs seem poorly understood.

1.8 Conclusion

RCT findings make a critical contribution to evidence based medicine but raise several ethical dilemmas that have historically resulted in a reluctance to adopt this method of experimentation. Paediatric RCTs have faced particular challenges, which stem from the vulnerable nature of the population and, owing to the relatively small numbers of children with a specific disease, the lesser potential for financial gain from the development of new therapies (Caldwell et al. 2004). Despite these concerns, it seems that the argument that Shirkey ([1968] 1999) began in the 1960s has now been won, and more RCTs involving children are being conducted.

If it is accepted that it is important to conduct paediatric RCTs, it follows that they should be carried out in such a manner as to allow robust findings to be generated. Ensuring adequate levels of recruitment, adherence and retention are three ways in which this goal can be met. However, as childhood conditions often affect small numbers of children a greater proportion of those who are potentially eligible for participation are needed to take part than is often the case in adult RCTs. Furthermore, the vulnerability of children to suffer exploitation during their participation has resulted in a greater number of regulations concerning their participation. Moreover, those who design and conduct paediatric RCTs rely upon more than one individual to provide consent for participation

and to carry out the trial activities after enrolment: depending on the age of the child participation requires the willingness of the child themselves and the child's parents.

It is evident from the literature that, whilst a substantial number of studies have explored recruitment to paediatric research, the majority have focused on therapeutic research, and in particular in the fields of oncology and neonatology. As I discussed earlier in this chapter, non-therapeutic research may present different challenges to therapeutic research, particularly in designs that do not involve the testing of medications. Although recruitment to paediatric RCTs has been the subject of a fair amount of investigation, adherence and retention have been less well studied, despite having a substantial influence on the quality of evidence that RCTs produce. It is from all these premises that the aims and objectives of this thesis were constructed.

1.9 Aims and objectives

This thesis aims to further understanding of recruitment, adherence and retention to non-therapeutic paediatric RCTs, with particular emphasis on the role of social context.

The objectives are to:

- Explore the role of families, trial staff, trial design and the wider context on recruitment.
- Consider the role of families, trial staff, trial design and the wider context on adherence.
- Consider how families, trial staff, trial design and the wider context influence retention.
- Investigate the relevance of the societal benefit versus personal benefit debate for participation in paediatric RCTs.

As I will describe in detail in Chapter 4, an ethnographic approach was taken to explore these objectives and two non-therapeutic paediatric RCTs were used as case studies for the research. These RCTs (Learning Early about Peanuts (LEAP) and Enquiring about Tolerance (EAT)) both explored whether early or delayed introduction of allergenic foods was the most effective method of preventing young children from developing food allergy.

1.10 Organisation of the thesis

In this introductory chapter I have outlined the background to the thesis, explored the literature regarding recruitment, adherence and retention in paediatric RCTs and presented the aims and objectives.

In Chapter 2, the literature review, I focus on one aspect of participation: the societal versus personal benefit debate that is common to dialogues regarding research participation.

Chapter 3 outlines the theoretical approach that underpins the thesis. In that chapter I explain why I chose Bourdieu's (1977; 1990) Theory of Practice to structure data collection, and why I used his theory alongside Titmuss' (1970) The Gift Relationship to analyse the data.

In Chapter 4 I present the methods used for data collection and analysis, describing the rationale for the ethnographic approach that was taken and how data were collected and analysed.

Chapter 5 outlines the fieldwork setting and describes the staff and parents who participated in the study, providing context to the study findings that follow.

Chapters 6, 7 and 8 are the results chapters and each deals with a different objective.

Chapter 6 explores recruitment to the RCTs, Chapter 7 considers adherence and Chapter 8 explores retention.

The results are discussed in Chapter 9, where the implications for practice, areas in which further research would be beneficial and limitations of the study are also examined.

Chapter 2: Literature review: societal benefit and personal benefit as models of participation

In the previous chapter I touched on a discussion that occupies the literature regarding RCTs: whether it is either right or acceptable for participation to be driven by a hope for societal benefit alone or whether individuals should benefit personally. In this chapter I further explore this debate by reviewing the theoretical and empirical literature. The SCOPUS online database was searched using the terms that are presented in Appendix 2. All articles that explored blood donation, organ donation or research participation and that were written in the English language were suitable for inclusion in the review. Titles and abstracts of returned articles were scrutinised and full text articles obtained for papers likely to be relevant. Reference lists of retrieved articles and review papers were also searched for relevant studies.

Although the focus of this thesis is participation in paediatric RCTs, in outlining the debate I also draw on theoretical literature that considers participation in other healthcare activities: research participation more generally, blood donation and organ donation. Along with research participation, blood and organ donation fall within a category of activities that are referred to as 'prosocial' (Goette et al. 2010; Lacetera and Macis 2010). Whilst there are fundamental differences between the three activities, there are also many similarities and the Nuffield Council on Bioethics (2011) considers that blood donation is a '*paradigm case*' (p.8) in informing assumptions about prosocial healthcare activities. When considering the involvement of children in RCTs, debates regarding models of blood and organ donation are perhaps more useful than those which consider participation in adult RCTs. Like paediatric RCTs it is not usual or in many countries legal

to incentivise participation in blood or organ donation with rewards that go beyond the immediate reimbursement of the costs that individuals incur when they take part (Nuffield Council on Bioethics 2011).

The literature regarding participation in prosocial healthcare activities has frequent references to, on the one hand, terms such as altruism (Gil-Diaz 2009; Guttman et al. 2011), warm glow (Ferguson et al. 2012), benevolence (Ferguson et al. 2008) and gift giving (Gill and Lowes 2008; Boas 2011) and, on the other hand, to financial rewards (Fry et al. 2005; Farrugia et al. 2010), benefits in kind (Nuffield Council on Bioethics 2011) and incentives (Festinger et al. 2009; Bruzzone 2010). For the purposes of this thesis I have categorised these terms into two groups. The first includes discourses that make reference to the altruistic type approaches or motives. As these reflect instances where individuals co-operate together apparently for the benefit of others rather than themselves, I have called this the 'societal benefit' model. The second I have called the 'personal benefit' model as these represent instances in which individuals draw personal advantage from their participation. The dichotomous categorisation reflects the way that the models are discussed in the literature. However, as I will discuss later in this thesis, these models often coexist.

In the following review of the literature I consider theoretical debates about which of the two approaches should be used to promote participation and the relative advantages and disadvantages of the models. I also examine the relevance of these debates with regards to the empirical literature that explores participation in paediatric RCTs.

2.1 The societal benefit model

The societal benefit model of participation in prosocial activities relies upon notions of solidarity and selflessness, where taking part is often viewed as 'gift giving' for the good

of others who are not known to those who participate (Titmuss 1970; Tutton 2002; Boas 2011). In this model individuals take part in activities to help others within society and with no hope of personal benefit or profit. Thus the approach is far removed from notions of economic markets, where participation is viewed by both the donor and recipient as representing a financial transaction or an opportunity for personal gain (Boas 2011).

Societal benefit has been placed at the heart of research participation, blood and organ donation by recommendations from the World Health Organization (WHO), World Medical Association (WMA), European Union (EU) Directives, and national legislation. The wording of the documents from each organization and for each of the three activities varies slightly but the essence remains the same: that participation should be voluntary, and, for this reason, usually unpaid (Nuffield Council on Bioethics 2011). Although it is acceptable for research participants to be financially rewarded for taking part in research, the caveat is that these rewards should not be sufficient to be coercive. Furthermore, EU legislation prevents children and other 'vulnerable' groups from receiving payment or other substantial incentives for research participation. As I go on to discuss in greater detail in the following paragraphs, the primary purpose of such mandates is to protect individuals from coercion and thus to maintain the voluntary nature of their participation. However, a secondary effect can be the promotion of societal benefit rather than personal benefit in these activities (Epstein and Danovitch 2009). For this reason Boas (2011) considers that the regulations represent '*altruism-based social policy*' (p.1378).

Whilst the aforementioned recommendations portray societal benefit models of participation in prosocial healthcare activities as an accepted standard, this notion is taken further in the theoretical literature. The essence of the argument is that to avoid 'free riding' individuals have an obligation and moral imperative to contribute to society

by, for example, joining the organ donor register, or agreeing to participate in research when invited. This is particularly the case if they themselves would wish to access donated blood or organs or healthcare that has been wrought out of research evidence (Harris 2005; Siegal and Bonnie 2006; Forsberg et al. 2009; Glannon 2009). The argument has also been used in practice. In the autumn of 2009 the UK organ donation campaign drew on this principle in a television advertisement aimed at recruiting volunteers to the organ donor register by stating:

Nearly all of us would take an organ but most of us put off registering. If you believe in organ donation - prove it. Register now.

[Organ donation television advertisement⁵]

With respect to research participation, Harris (2005) is particularly critical of free riding and argues that current discourses and practices that focus on altruism or that view research participation as supererogatory compound the problem. He suggests that, providing research is well designed and regulated, the potential for those who take part to be harmed is minimal. Rather than a risky activity in which participation is beyond the call of duty, participants are simply fulfilling a moral duty to help protect society from ill health (Harris 2005). He includes children's research participation within this line of reasoning, arguing that it is wrong to presume '*moral turpitude*' in children who are too young to express a view about their own participation (Harris and Holm 2003 p.125).

Whilst Harris (2005) says that he does not suggest that individuals should be legally required to take part in research, the notion of a more 'enforced' societal benefit approach to participation in prosocial healthcare activities is evident in practice. This is particularly apparent in relation to organ donation, for which several European countries

⁵ <http://www.guardian.co.uk/media/video/2009/oct/30/organ-donation-tv-ad> (accessed 6th June 2011)

have moved away from 'opt in' systems, to 'opt out' models in the hope that this will improve the number of organs that are donated. Under opt out systems consent for participation and thus acceptance of a societal benefit model is presumed unless individuals specifically state an objection (Cronin and Harris 2010; Petersen and Lippert-Rausmussen 2011; Bilgel 2012). This approach to organ donation has also been proposed in the UK via Bills that were put before Parliament in 2004 and 2009, although neither Bill progressed significantly (Cherkassky 2010).

Similar opt out models have also been discussed with respect to improving the numbers of people who take part in research. The approach has been used as a means of contacting potentially eligible research participants (Junghans et al. 2005; Trevena et al. 2006) and as a way of conducting RCTs, through a system known, after Marvin Zelen who proposed it, as Zelen randomisation. In this system individuals who are eligible to participate in an RCT are randomised, without their knowledge or consent, to the trial intervention or to standard care. Only those randomised to the intervention are subsequently approached regarding the trial and are given the opportunity to provide or withhold consent. Those who refuse consent receive standard care and data from all three groups of participants (those randomised without their knowledge to standard care, those who are randomised and consent to the intervention, and those who are randomised but refuse participation) are included in the final analysis (Zelen 1979).

Owing to ethical concerns, Zelen randomisation is rarely used in practice (Homer 2002). An exception is trials in which acquiring informed consent could invalidate randomisation, such as trials of behavioural interventions (Campbell et al. 2005). Opt out models are also used in trial designs where acquiring individual consent is not feasible, such as when

investigating whether an intervention works at a population, rather than individual, level (Cassell and Young 2002).

Empirical studies exploring whether the general public would support more enforced societal benefit models of involvement in prosocial healthcare activities reveal variable results. A public consultation by the UK Organ Donation Taskforce found that 60% of the population would support an opt out model providing it was properly implemented to protect the vulnerable (Cherkassky 2010). In an interview study of parents who had been approached to enrol their children in neonatal trials that had used standard consent and randomisation practices, Snowden et al. (1999) found that parents were evenly split regarding the acceptability of Zelen randomisation. However, those whose children had been randomised to the control arm of the actual trials had more objections to the Zelen method than those whose children had been randomised to the intervention. Snowden et al. (1999) argue that this finding suggests that parents from whom consent for participation would not have been sought if the Zelen method of randomisation had been used were less positive about the method than those who would have been asked to provide consent. The hypothetical nature of the question may also have influenced parent's views in this regard.

The lukewarm support that opt out models have received may reflect concerns, also posed in the theoretical literature, that societal benefit approaches compromise the autonomy of participants (see for example Treweek et al. 2010; De Wispelaere 2011). They also reflect the relevance of trust in the medical community for participation in prosocial healthcare activities, a notion that has been found to be important in many studies, including Gamble et al's (2012) survey of parental views of a deferred consent model of research participation. The backlash that occurred against the practice of

retaining, without the consent of the parents, the organs and tissues of children who underwent post mortems at certain UK hospitals serves as a cautionary tale with respect to enforced societal benefit models aimed at improving participation in prosocial healthcare activities. Parents told the inquiries that their greatest objection was not that the organs had been kept *per se*, but that they had been taken without their consent. Many said that if they had been asked whether they could be kept for research or teaching purposes they would probably have agreed (Seach Leith 2007).

The alternate and opposite extreme of the societal benefit model is the personal benefit model. In the following section I will discuss this approach further, considering arguments that both favour and oppose the model in comparison to the societal benefit approach.

2.2 The personal benefit model

In the personal benefit model individuals obtain either monetary or non-monetary rewards through participation in prosocial healthcare activities. The use of incentives, particularly financial incentives, has a relatively long history as a means of improving participation in prosocial healthcare activities, although the practice has fluctuated in popularity. Following an initial acceptance of personal benefit approaches they later came to be seen as unethical, exploitative and, in some instances, to lead to unsafe practice. The view that personal benefit approaches led to unsafe practice was strongly influenced, with respect to blood donation at least (Farrugia et al. 2010), by the publication in 1970 of Titmuss' 'The Gift Relationship'. In this study he highlighted that more recipients of blood transfusions contracted hepatitis when blood was collected under a system which offered financial rewards to donors than was the case for patients receiving blood that had been collected under a societal benefit model (Titmuss 1970).

Allowing individuals to personally benefit from participation in prosocial healthcare activities, particularly with respect to the receipt of incentives, has also raised concerns about commodification, coercion and exploitation.

2.2.1 Commodification, coercion and exploitation

One of the primary worries of those who oppose personal benefit models of participation in prosocial activities is that offering incentives, particularly substantial sums of money, in exchange for the donation of human material allows body parts to be viewed as consumer goods that can be bought or sold at will (Cynowiec et al. 2009; Bruzzone 2010; Boas 2011). This 'commodification' changes societal perception of the body from something that is '*intrinsically human*' to an object that may be owned (Hoeyer 2007 p.327). This compromises the dignity of those who participate in prosocial healthcare activities (Cynowiec et al. 2009) and such practice is, in the view of Boas (2011), the '*lowest form of capitalism*' (p.1378).

The view that personal benefit models of participation in prosocial healthcare activities are coercive and exploitative is central to the commodification argument and reflects concerns that the incentives, particularly financial incentives, may be irresistible to potential participants (Bernstein 2003; Wong and Bernstein 2011). This is of particular concern when considering the inequalities that exist in most societies. There is evidence that groups considered vulnerable to exploitation such as children, those with low incomes, or those marginalized by society are encouraged to take part when, under different circumstances, they would choose not to (Boulware et al. 2002; Matas 2012). Under these conditions participation can no longer be viewed as voluntary (Hippen et al. 2009) and thus the ethical guidelines and regulations set up to protect those who take part in prosocial healthcare activities are breached.

With respect to the payment of research participants specifically, several authors have argued that, although cases in which individuals have participated in research to obtain financial reward and have subsequently suffered harm do exist, the significant issue is not that a financial incentive was offered but that the research itself was either badly designed or poorly conducted (Harris 2005; Elliott and Abadie 2008; Arnason and Van Niekerk 2009; Taylor 2009). The findings of studies exploring whether incentives improve participation in adult research suggest that offering financial incentives increases willingness to participate but does not interfere with the voluntariness of the decision (Grady 2001; Bentley and Thacker 2004; Halpern et al. 2004). Cryder et al. (2010) found the size of the financial incentive offered had a positive influence on participants' decisions to take part in research. They also found that, although studies with large payments were viewed as more risky than those offering smaller financial rewards, participants actually spent more time looking at the risk information provided about the study. The findings of a study by Festinger et al. (2009) suggest that offering financial incentives may facilitate an ethical approach to participation by improving participants' understanding and recall of the purpose, risks and benefits of research. As the authors of the study suggest: *'it pays to remember'* (p.99).

The majority of the literature exploring commodification, coercion and exploitation makes reference to the use of financial incentives, but similar arguments have also been applied to 'desperate volunteers' (Minogue et al. 1995). This label has been awarded to those who participate in research to access healthcare, particularly potentially lifesaving treatment which is unavailable outside the research setting, for whom the voluntariness of participation has also been called into question (Grady 2001; Allmark and Mason

2006b). I will discuss this argument in greater detail in Section 2.4.3, which explores the literature regarding children's participation in RCTs.

Although the commodification argument is persuasive, there is evidence in the more recent theoretical literature that personal benefit models of participation are again receiving significant support (see for example Buyx 2009; Hippen et al. 2009; Omar et al. 2011). Some suggest that personal benefit underpins almost all participation in prosocial healthcare activities and that societal benefit discourses simply act as a socially acceptable façade (Epstein and Danovitch 2009; Farrugia et al. 2010; Matas 2012).

Proponents of the personal benefit model generally put three reasons forward in support of its use: supply and demand, autonomy, and justice.

2.2.2 Supply and demand

This argument draws on economic theory and applies market principles to resolve the deficit between the number of people who are willing to participate in prosocial healthcare activities and the number of people who are needed to meet the demand (Cherry 2009; Draper et al. 2009; Epstein and Danovitch 2009; Schicktanz and Schweda 2009). Those who advocate this model highlight the inadequacy of societal benefit approaches in meeting the needs of populations and the effectiveness of personal benefit models in ensuring an adequate supply of participants (Arnason and Van Niekerk 2009). They also argue that, whilst personal benefit models of participation will usually incur costs that are not relevant to societal benefit approaches, these are offset by the savings made to the health service and society by improving societal health more generally (Cynowiec et al. 2009; Petersen and Lippert-Rausmussen 2011).

Others use the notion of 'crowding out' to counter the idea that personal benefit models of participation help to overcome the gap between supply and demand in prosocial

healthcare activities. They suggest that crowding out will occur if the dominant model for involvement followed a personal benefit approach because those who would only participate for altruistic reasons would be less likely to do so; these participants are 'crowded out' from participating and thus the overall pool of participants is reduced (Buyx 2009; Chmielewski et al. 2012). There is limited evidence to support such claims. When examining organ donation practices Boas (2011) argues that crowding out does exist because the 'one for one' model of organ donation, in which living donors give organs to a specific individual, is slowly overtaking the 'one for all' model of deceased organ donation. However, he neglects to consider that the increase in living organ donation may reflect altruistic donations between relatives or friends. Chmielewski et al. (2012) also found evidence of crowding out when exploring the acceptability of incentives for blood donation during interviews with 66 Australian adults. These individuals considered they would be less likely to donate if financial incentives were to be offered, although these findings may have been influenced by the study design; the use of interviews may have resulted in social desirability bias.

2.2.3 *Autonomy*

A second argument in favour of personal benefit models, including financial payments, for participation in prosocial healthcare activities revolves around the rights of individuals to use their bodies as they wish (Arnason and Van Niekerk 2009; Hippen et al. 2009; Iltis 2009; Phillips 2011). In response to concerns that personal benefit approaches compromise an individual's autonomy by coercing them to participate, Cherry (2009) argues that the societal benefit model of organ donation '*embraces contradictory positions*' (p.651) by asserting that individuals have the autonomy to choose whether or not to donate *per se*, but are not sufficiently autonomous to resist the lure of financial incentives. He also suggests that concerns about commodification are futile. The very

nature of these prosocial activities instrumentalises the human body; paying donors cannot alter this unequivocal fact (Cherry 2009). Moreover Cynowiec et al. (2009) argue that an individual's autonomy is equally likely to be compromised by pressure from a family member to make an 'altruistic' donation of a kidney to a relative as by a stranger offering them a financial incentive.

2.2.4 Justice

The third argument in support of personal benefit models underpinning involvement in prosocial healthcare activities emphasises the valuable service that participants provide. Several authors highlight that individuals such as fire fighters or miners who take part in risky activities for the good of society are not expected to do so without recompense (Arnason and Van Niekerk 2009; Cherry 2009). Others argue that, by failing to reward participants, societal benefit approaches are themselves exploitative, unjust (Grant and Sugarman 2004; Phillips 2011) and could be viewed as theft (Taylor 2009).

This argument is particularly evident in debates around research participation, especially with respect to biobanking, where substantial financial gains may result for research organisations using data and samples provided by individuals who do not benefit themselves because they were donated under a societal benefit model (Forsberg et al. 2009). Several legal cases have been brought before the courts in the USA arguing for the rights of participants to benefit from the patenting of their genetic material (Schleier 2009). In *Moore v University of California*,⁶ a patient with leukaemia attempted to sue the University after a researcher created a cell line from tissue that was removed from him during a medical procedure and the University patented this cell line which subsequently

⁶ *Moore v Regents of the University of California*, 793 P2d 479 (Cal 1990)
<http://online.ceb.com/CalCases/C3/51C3d120.htm> accessed 14th May 2012

had great commercial value. Similarly in *Greenberg v Miami Children's Hospital Research Institute*,⁷ parents and support group organisations brought a case against an individual researcher and the research organisation that patented the genetic sequence of Canavan disease. The plaintiffs argued that parents had consented to their children providing samples and data for research purposes to help advance medical knowledge of the condition and thus benefit the population at large, a notion that was compromised by patenting. Furthermore they proposed that the research institute was 'unjustly enriched' by the patenting of the donated samples. Although neither set of claims were upheld, they highlight the questions that exist regarding whether it is just for researchers or organisations to profit financially when those who donate samples do not.

In addition to the literature exploring the relative merits of personal benefit or societal benefit approaches to participation in improving the number of volunteers and ensuring participants are treated fairly, there is also a body of work which discusses whether the approach that underpins participation in prosocial healthcare activities is relevant to wider societal practices and values.

2.3 Models of participation in prosocial healthcare activities and wider societal practices and values

Some suggest that the approaches underpinning participation in prosocial healthcare activities both reflect and influence societal values more generally. That these models of participation reflect societal values is perhaps self-evident. Epstein and Danovitch (2009) argue that those who consider altruistic approaches to organ donation to be ineffective because they have failed to meet the demand ignore the fact that the lack of supply stems from '*pervasive commercialization*' (p.357). Boas (2011) suggests that the rise in

⁷ *Greenberg v Miami Children's Hosp. Research Institute, Inc.*, 264 F Supp 2d 1064 (SD Fla 2003) <http://indylaw.indiana.edu/instructors/orentlicher/healthlw/Greenberg.htm> accessed 14th May 2012

the practice of living organ donation, at a time when rates of deceased organ donation are stable or falling, is the result of personal social capital and networking eroding altruistic practices in society in general.

Titmuss (1970) was the first to suggest that the model underpinning prosocial healthcare activities could influence wider societal values and practices when he asserted that societal benefit models of blood donation could stimulate social cohesion and solidarity within the wider community. A similar line of argument is evident in the more recent literature. Healy (2000) argues that blood collection practices that use societal benefit models embed altruism in society by providing individuals with an opportunity to behave in ways that benefit others. Hippen et al. (2009) suggest that society as a whole will suffer if it promotes or allows vulnerable people to sell parts of their body to obtain money for life's basic essentials. If it is deemed acceptable for individuals make money in this way, then the current social responsibility to help those in need may be withdrawn (Hippen et al. 2009).

Whether societal or personal benefit models of participation are superior in terms of increasing the number of individuals who take part in prosocial healthcare activities and in ensuring the just treatment of participants is a theoretical debate that has been ongoing for some time without resolution; convincing arguments exist for the use of both approaches. In the following section I explore whether the empirical literature regarding participation in paediatric RCTs can help to resolve this debate.

2.4 Models of participation in paediatric RCTs

In the previous sections I discussed how societal benefit and personal benefit models have been debated with regards to improving participation in prosocial healthcare

activities in general. Specific aspects of the previous debates are particularly pertinent when considering how these models relate to children's participation in research.

The Declaration of Helsinki (World Medical Association 2008) states that those who are unable to provide consent for participation (a category into which children often fall) should only be included in research from which they are unlikely to benefit if the risks are minimal, the research will help the population they represent, and the research cannot be carried out by those who are able to provide consent. The subtext of this recommendation is that it is both acceptable and desirable for children who take part in research to personally benefit from their participation. On the other hand, however, the Declaration also states that participation should be voluntary and that no undue influence should be used to encourage individuals to take part. Thus a dichotomy exists in the guidelines for paediatric research participation that is relevant to the existence and use of societal or personal benefit approaches in this field.

Concern about unduly influencing participation has a bearing on personal benefit models of participation in paediatric research. Although children who take part in RCTs in countries such as the USA may receive incentives, including financial payment, for their participation, legislation states that children taking part in research in EU member states should receive '*no incentives or financial inducements [...] except compensation*' (European Parliament and the Council of the European Union 2001 p.L121/38). However, whilst offering substantial financial payments to the families of children who participate in research is a relatively clear example of an inducement, defining what counts as an incentive for participation is not always so straightforward. This matter is the subject of several papers produced by those involved in paediatric research, particularly those who conduct research in the USA where, although it is legally acceptable to offer incentives to

children and their families who participate in RCTs, concerns about the ethics of offering undue inducements still exist. Such worries reflect the idea that offering incentives may lead parents to make decisions that overlook the best interests of their children (Caldwell et al. 2004; Diekema 2005) or distort the decision making processes of children who are themselves old enough to choose whether to participate (Wendler et al. 2002; Itlis et al. 2006). To overcome this problem several authors suggest that reimbursement of expenses, appreciation payments of nominal value, or age appropriate gifts such as books, art materials, or vouchers, offer less risk of coercion than payment of substantial sums of money (see for example Wendler et al. 2002; Ramsey 2006).

Although the ethical guidelines and principles that guide paediatric research seem to favour a personal benefit model of participation, this model has caveats. Whilst it is acceptable and even expected that children who take part in trials should benefit, the extent of these benefits should not be so great that they form an undue inducement. In the following sections I review the empirical literature regarding participation in paediatric research to explore the extent to which societal benefit and personal benefit models are evident.

2.4.1 Evidence that participation is underpinned by societal benefit

Several studies report that parents take part in research to help future generations of children. Benefitting future children was important to parents answering forced choice questions about their motivations for enrolling their children in research (Harth and Thong 1990; Langley et al. 1998; van Stuijvenberg et al. 1998; Sammons et al. 2007), and has been discussed by parents during qualitative interviews about their motivations for enrolling their children in research (Glogowska et al. 2001; Taylor and Kass 2001; Deatrick et al. 2002).

The societal benefit model is also characterised by parental readiness to contribute to science or medicine. In a questionnaire study of parents who enrolled their children in clinical asthma research, Rothmier et al. (2003) found that a desire to advance medical knowledge positively influenced parents' decisions. Similarly parents who enrolled their children in one of two vaccine trials told Chantler et al. (2007) that they wanted to help to advance medical knowledge, a finding that the authors hypothesised was related to parents' own medical and scientific backgrounds.

Parents who were interviewed for Chantler et al.'s (2007) study also considered their participation to be a '*social responsibility*' (p.315). Other studies have reported similar findings. Parents described consenting to their child's participation in RCTs to repay the contribution that previous families had made to advancing medical knowledge, progress from which their children had benefitted (Jollye 2009; Woodgate and Yanofsky 2010).

The empirical literature does show that societal benefit is relevant to parental willingness to enrol their children in RCTs, although this finding may be influenced by the design of the included studies. Many used forced choice questionnaires in which societal benefit type responses were amongst the options from which parents could choose.

Furthermore, and particularly with respect to the qualitative studies that gathered data using face to face interviews, parents may have wished to provide socially acceptable reasons for participation.

Whilst a substantial body of work suggests that societal benefit motivates parents to enrol their children in research, there is also a relative abundance of empirical literature in which parents describe consenting to their child's participation in an RCT for reasons which fall within the remit of the personal benefit model.

2.4.2 Evidence that participation is underpinned by personal benefit

There is substantial evidence in the empirical literature that a hope for personal benefit motivates parents to consent to their child's participation in research and, as for societal benefit models, this is manifest in a variety of ways. Two studies have considered whether financial incentives affect parental willingness to consent to their child's participation. Williams et al. (2008) found that sites that offered financial incentives for participation in a multicentre trial of paediatric HIV treatments in the USA were more successful at recruiting than those that did not. Rothmier et al. (2003) found that parents who were invited to enrol their children in a trial of asthma medication in the USA and who completed a Likert scale questionnaire about their motivations were positively influenced by financial incentives and the opportunity to access free medications, a factor that was more influential for parents with lower incomes than for those with higher incomes.

The opportunity to access free healthcare also acts as an incentive for parents to enrol their children in research, particularly when parents live in countries where healthcare incurs a cost at the point of delivery. In their ethnographic study of the reasons that parents enrolled their children in vaccine research in the Gambia, Fairhead et al. (2006) found that parents' main motivation was to access free healthcare, with the aims of the research being viewed as almost inconsequential. Masiye et al. (2008) established similar findings in their focus group study of 81 mothers whose children were enrolled in clinical trials of malaria treatments in Malawi. These mothers participated to receive the best treatment, free medical care and other free incentives such as money and gifts.

The opportunity to obtain free healthcare appears less relevant for parents living in the UK where, unlike Malawi and the Gambia, healthcare incurs no cost at the point of

delivery. However, their motivations do still reflect the potential for personal benefit.

Parents living in the UK considered that research participation provided an opportunity for their child to receive closer monitoring and was a more convenient way to access standard healthcare (Chantler et al. 2007). Parents also considered care within a trial to be of superior quality to standard healthcare. Those interviewed by Glogowska et al. (2001) about their views of research felt that they would receive better care if they enrolled their children in a UK trial of speech and language therapy than if they did not. Similarly parents living in the UK who completed a retrospective postal questionnaire regarding the reasons they allowed their children to take part in vaccine research rated 24-hour access to medical staff and the ability to receive childhood immunisations at home as reasons they chose to participate (Jay et al. 2007).

The opportunity to access the newest medications is another way in which children benefit personally from participation in paediatric RCTs. Parents interviewed by Chantler et al. (2007) said that they consented to their child's participation to access a new vaccine for meningitis that was not available outside the research setting. The motivational force that access to novel therapies has on parental willingness to enrol their children in research is particularly evident in studies involving parents whose children had life threatening or life limiting conditions. Schaffer et al. (2009) analysed the websites of parents whose children had cancer or life limiting genetic disorders and found that many had enrolled their children to access medications that might help to save their lives. This was particularly true if they had exhausted all therapies that were available outside of a clinical trial. Similarly, parents who were living in the USA, had enrolled their children in phase 1 oncology trials and who were interviewed by Deatrick et al. (2002) suggested they were motivated by the potential to access medications that may prolong, if not save,

the lives of their children. Parents whose children had life limiting conditions such as HIV (Taylor and Kass 2001) or who required a bone marrow transplant (Stevens and Pletsch 2002) also described agreeing to their child's participation in research trials that were being conducted in the USA as a last attempt to save their life.

The findings of only one study suggest that the personal benefit model of participation is not always viewed positively by parents who are invited to enrol their children in an RCT. Parents who were interviewed by Nabulsi et al. (2010) about potential participation in vaccine research in Lebanon expressed concern at the integrity of research where incentives (free travel and free vaccines) were offered. They considered that this would act as a barrier to their participation.

Although the majority of literature in which participation is underpinned by personal benefit relates to parental willingness to enrol their children in an RCT, two studies, both conducted in the USA where healthcare is not free at the point of delivery, have found the model to be relevant for trial retention. When asked to describe why they continued to facilitate their child's participation in a trial of HIV medications, parents told Geromanos et al. (2004) that access to healthcare and monitoring of their child's health status made continuing with research participation worthwhile. Access to free glasses and the completeness and quality of the care provided within a trial evaluating the most effective means of correcting myopia were rated as reasons for remaining within the trial by parents who completed a questionnaire about their experiences of participation (Dias et al. 2005).

2.4.3 Personal benefit by default

The empirical literature highlights that parents are driven to enrol their children in RCTs because they, or more commonly their children, will benefit from participation. This

suggests that, in ensuring that parents and children are not coerced into participating in RCTs by promises of material incentives such as gifts, the enticing power of the trial itself may have been overlooked.

The literature also suggests that the incentives offered by the trial designs might be coercive. This is true when the benefits relate to accessing healthcare and particularly when parents use research participation to access treatments they hope will extend or save the life of their child. Parents interviewed by Snowden et al. (2006) who had been invited to enrol their infants in neonatal trials described agreeing to participate out of fear for their child. Zupancic et al. (1997) found that parents who took part in neonatal research considered their children to be more unwell than those who did not consent to their child's participation. Parents living in North America who took part in telephone interviews regarding their decisions to enrol their neonates in 'above risk' trials described doing so because they felt they had no other option (Ward 2009).

The acceptability of a research design incentivising trial participation has been debated in the law courts in the case of *Grimes v Kennedy Krieger Institute* that was described in the previous chapter. The consent form of this trial highlighted several aspects of the design that parents may have found attractive, including a clause which informed parents '*your house is going to have special repairs in order to reduce expose to lead in paint and dust*' (Spriggs 2004 p.178). The judge's concern that the study was coercive to low income families, and that coercion by trial design was an inherent risk of research, led him to rule that parents could no longer consent to their children's participation in non-therapeutic research, although this ruling was later overturned (Spriggs 2004).

Whilst the aforementioned literature seems to provide evidence that the design of research may be coercive to parents, particularly those who find themselves in situations

of extreme difficulty, other studies counter this argument. Studies which reported that parents described having no choice but to enrol their children in a trial also found that parents viewed research participation positively, as an activity that offered a chance to 'buy time' with their child (Deatrick et al. 2002; Oppenheim et al. 2005). Furthermore, some parents with terminally ill children actively sought out experimental research, lobbying the Federal Drug Administration (FDA) in the USA to be allowed to enrol their children in clinical trials (Schaffer et al. 2009). As Spriggs (2004) argues, in an unequal society the incentives offered by a research design may be '*mutually advantageous and consensual*' (p.179) rather than coercive or exploitative. This point is neatly articulated in a newspaper article by Denise Grady (2000) who quotes Dr Christian Barnard's justification of the actions of those who were pioneers for heart transplants:

A person being chased by a lion to the edge of a river would jump in and try to swim across even if the river was full of crocodiles, but would never jump in if there were no lion.

Thus, in situations of inequality such as those described in the empirical literature, for example when parents cannot afford to pay for healthcare or their child's health is threatened, it might not be that the opportunity to benefit from research is coercive or exploitative. Rather it is the position that the parents find themselves in that is unjust. Unfortunately the designs and level of detail provided by the empirical studies reporting that personal benefit motivated parents to enrol their children in the trials do not make it possible to establish whether this is the case. These studies did not set out to explore such issues and additionally did not gather data on the role of contextual factors on parental decisions to enrol their children in the trials.

2.5 Conclusion

It is apparent that both societal benefit and personal benefit models underpin participation in prosocial healthcare activities. Each has its own advantages and disadvantages, not only in promoting participation, but also with regards to the just treatment of participants. When considering participation in paediatric RCTs, ethical and legislative principles may lead to confusion regarding the acceptability of the two models because they suggest that it is acceptable for those who take part to benefit, but that these benefits should not be sufficient to offer an undue inducement.

There is certainly evidence that societal benefit is important to parents who enrol their children in RCTs, but this does not seem to be the most important factor. Parents in many studies that explored decisions about consent to research were clearly motivated by a personal benefit model of participation. As a narrative synthesis of qualitative studies exploring the reasons parents enrolled their children in RCTs found, the motivational force of the societal benefit model appears to be dependent upon context. Parents of children with life threatening or life limiting illnesses often considered societal benefit to be secondary to the opportunity to help their child (Fisher et al. 2011: Appendix 3). Thus, although ethical and legislative guidelines exist to minimize the coercive power of personal benefit models of participation in research, it seems that it is the benefits offered as a consequence of participation that has the greatest influence on parents, an aspect that is more difficult to control.

To date the majority of studies have explored the views of parents whose children had an underlying health complaint, and there is a particular focus on parents whose children have life threatening or life limiting illnesses. This bias may have influenced the finding that personal benefit models are more relevant than societal benefit models. For these

parents participation was often viewed as a 'last chance' to save their child, although studies also found that parents with terminally ill children valued the chance to contribute to society (Deatrick et al. 2002). The designs of the studies, the majority of which used questionnaires with fixed choice questions also limit the utility of the findings. Such studies do not establish whether parents themselves recognised the potential for personal benefit, or whether the way in which they were invited to enrol their children in the trials and/or the wording of the questions used in the questionnaires influenced their thinking. Furthermore, whilst personal benefit and societal benefit have been discussed extensively in relation to acquiring consent to participation in research, few studies have considered the role that they play in adherence or retention.

Although this literature review has focused on the relevance of societal and personal benefit approaches, several authors point out that willingness to participate in prosocial healthcare activities does not solely relate to this dialogue. Other factors, such as trust, or the lack of it, in healthcare organisations is also relevant (Boas 2011; James et al. 2011; Lipworth et al. 2011). With respect to blood donation practices, Healy (2000) argues that the organisational side of donation is ignored at the expense of focusing on donor motivations or characteristics. He considers this approach to be inadequate because, when considering the sociodemographic profiles of blood donors, more individuals who share the characteristics of donors will choose not to donate than is the case for those who do donate. For example, for every White British man aged between 31 and 40 who donates blood, there will be a large number of White British men aged between 31 and 40 who do not. He also highlights that the collection practices of blood donor programs influence the motivations of those who take part: if no incentive is offered for participation then donors are likely to cite altruistic motives for their participation. He

considers that studies exploring these practices should take account of the social framework that provides the opportunities or constraints for those who organize and participate in blood donation, a view that is expressed by others in relation to biobanking (Lipworth et al. 2011; Tutton and Prainsack 2011).

These arguments are also pertinent to participation in research for which, until recently, studies have tended to focus solely on the participant or potential participant and perhaps the design of the trial, but disregarded the influence of trial staff and wider social practices. Studies that have taken a wider view have found that staff may influence both recruitment (Snowdon et al. 2006a; Shilling et al. 2011) and adherence in RCTs (Lawton et al. 2011). For all these reasons, when planning the research that underpins this thesis, a design and theoretical model were chosen that would promote an understanding of not just the views of parents or staff but also of the wider context. I aimed to explore the influence of the backdrop against which the trials were being conducted and the interactions between parents, researchers, funders and wider society on recruitment, adherence and retention. The design of the study is discussed in Chapter 4, but first, in the following chapter, I outline the theoretical models that were used to guide data collection and analysis.

Chapter 3: Theoretical Frameworks

When choosing the theoretical framework that would underpin this thesis, I wanted to use a theory that would promote and support the ethnographic approach that I believed to be the most appropriate method of collecting data.⁸ In considering the most appropriate theory for the study I initially turned to the existing empirical literature to see whether this could help my decision.

A review of the literature revealed that many studies have found parental perception of risk to be relevant to recruitment. As legislation and ethical guidelines pertaining to paediatric research also place substantial emphasis on risk minimisation, I initially considered that risk theories, in particular Beck's (1992) theory of risk, would be appropriate. Beck's theory consists of three main tenets: that the modernization of society has resulted in the increase of undetectable risks; that changes in society have resulted in 'individualization' where individuals must construct their own lives; and that society is now experiencing 'reflexive modernization' in which the processes of modernity that produce risks are considered and critiqued. Although Beck's theory refers predominantly to the risks brought about following industrialisation, similarities were evident with the risks of research participation, and with the topic that the case study trials were investigating: food allergy. Both research and food allergy have been identified as proffering undetectable risks; this notion has been discussed by parents who chose not to consent to their child's research participation (see for example Chantler et al. 2007; Snowdon et al. 2007) and by parents of peanut allergic children (Avery et al. 2003). As others have discussed Beck's theory with regards to the sociological investigation of food

⁸ Justification for the method is provided in Chapter 4

allergy, with particular reference to reflexive modernization (Rous and Hunt 2004; Nettleton et al. 2009), it initially seemed that Beck's (1992) theory of risk might be suitable.

However, there were some limitations to using this theory. Green (2009) argues that structuring a study using risk theory both constrains the ability to understand the social world because factors other than risk are ignored, and pre-empts the answers generated by empirical study. I also felt that risk theories would not facilitate the broad understanding of research participation that I hoped to achieve. Furthermore risk theory might limit investigation of the social context, an aspect of participation that several authors have highlighted as important to participation in prosocial healthcare activities (Healy 2000; Lipworth et al. 2011; Tutton and Prainsack 2011). I thus decided that a theory that encouraged an extensive investigation of research participation would be more useful.

Bourdieu's theory of practice seemed an appropriate framework for several reasons. Firstly, as I discuss in greater detail later, this theory stems from Bourdieu's fundamental belief that those wishing to understand the practices of others should focus on both social rules and individual choices and perceptions (Bourdieu 1977). By promoting an examination of the context in which participation is occurring, I believed that his theory would encourage an alternative to the predominantly subjectivist approaches⁹ that have been adopted in the empirical literature regarding paediatric RCT participation to date. Furthermore, the key concepts of habitus, field and capital (discussed in detail in Section 3.1) seemed to fit well with the ethnographic approach, promoting breadth during data collection and analysis. Bourdieu's notions of capital and the exchange of capital also

⁹ i.e. the exploration of the personal views and characteristics of the parents and researchers.

seemed relevant to the societal versus personal benefit debate that was evident in both the theoretical and empirical literature.

At an early stage in my PhD, before I began collecting data and when I was still considering which theory would be most useful, I had an informal conversation about the study with a parent whose child was participating in one of the RCTs which I would be using as a case study for the research. She asked what my research was about and I explained that, as well as understanding what influenced trial recruitment, I also wanted to learn more about why parents continued to facilitate their children's participation in the RCT, which was longitudinal in design and had been ongoing for some years. I told her that a colleague had suggested this second objective was pointless because he considered that parents would continue taking part in research for the same reason they had initially decided to participate. The mother told me that in her case that was not true. She had decided to enrol her son in the trial because she recognised that he would obtain expert care for his food allergies and eczema that was not readily available outside the research setting. However, as he had now grown out of these conditions, their need for care had resolved. She said that she continued to participate because she had signed up to the trial and *'that's the sort of people we are'* [Diary 2nd January 2010]. This conversation highlighted to me the potential relevance of Bourdieu's theory. Based on our limited discussion, her participation appeared to have been influenced by both social context (the lack of expertise in managing her child's health), and by her personal values that she should fulfil her commitment to the trial. Our conversation helped to convince me that Bourdieu's theory was likely to be a useful framework for the study.

In the following sections I describe Bourdieu's theory of practice in more detail and discuss ways that it has been applied within the healthcare literature. I also discuss the limitations of the theory.

3.1 Bourdieu's theory of practice

Bourdieu did not provide a clear definition of the term 'practice' within his work.

However, in his conversation with Loïc Wacquant, his one time student and later collaborator, he did describe how practice is found in both what an individual does, their '*opus operatum*,' and in the way that they do it, their '*modus operandi*' (Bourdieu and Wacquant 1992 p.215). He developed his theory of practice because he considered explaining the social world from either an objectivist or subjectivist viewpoint was inadequate. Rather, he argued, practice is influenced by a combination of the social environment, an individual's personal beliefs which are derived from culture and traditions and, furthermore, the interaction between these positions (Bourdieu 1977). These influences are reflected in the three main concepts, habitus, capital and field, which he used as the tools of his theory. In the following sections I describe each of the concepts before explaining how they interact with each other in Section 3.1.4.

3.1.1 *Habitus*

Bourdieu (1977) developed the notion of habitus, which he used both in the singular and plural, to explain that individuals do not behave independently of the social world. He defined habitus as '*systems of durable, transposable dispositions, structured structures predisposed to function as structuring structures*' (Bourdieu 1977 p.72). Although this definition is somewhat opaque, essentially habitus are characteristics, values or views that are formed using past and present experiences and which, due to their lasting and transferable nature, influence present and future practices (Maton 2008). Habitus are

dynamic in nature and develop continuously with each new experience, although early life events such as family practices and schooling are particularly important to their development (Bourdieu 1977).

Habitus may be personal or collective. They are constructed not only by individual experiences, but also by shared experiences such as belonging to a particular social class, race or gender. In this way habitus generates all '*reasonable, commonsense behaviours*' whilst excluding '*the behaviours that would be negatively sanctioned*' (Bourdieu 1990 p.55-56). Habitus are not confined to individuals. Rather, the practices of organizations and institutions are also informed by the shared organizational values.

Habitus are both developed and influence practice in a subconscious and uncalculating manner (Bourdieu 1977). When coupled with the experiential nature of their development, habitus predisposes individuals to behave in a particular manner; it causes them to act almost without thinking about the course of action they are taking (Bourdieu 1990). This is particularly true when people find themselves in situations that echo a social world they consider familiar. In this situation '*the habitus finds itself as a fish in water, it does not feel the weight of the water and takes the world about itself for granted*' (Wacquant 1996 p.216). Consequently the practices of individuals with comparable backgrounds tend to be synchronized because, although each person acts according to their own values and dispositions, there is a strong concordance between their habitus.

Perhaps one of the most important facets of habitus is that the influence it exerts on practice should not be viewed in isolation; it is both context dependent and temporal. The same dispositions can result in very different practices depending on the state of the field and can be, albeit unwittingly, adjusted according to the particular environment. For

example, teenagers may have different values when acting within their peer group than they do with their family (Reay 2004). Bourdieu (1990) thus stressed the importance of considering habitus (the subjective influence) in relation to the field (the objective influence) in which a practice is occurring.

3.1.2 *Field*

Bourdieu defined the field as '*a network, or a configuration, of objective relations between positions*' (Bourdieu and Wacquant 1992 p.97). Essentially it is both an area where social activity takes place and the relations of power that are held by those who produce the social activity. A field may be actual and tangible (e.g. a hospital or school) or symbolic and intangible (e.g. academia or healthcare). The social world is made up of many different fields, which overlap and interact together, each having its own philosophy or habitus, which informs and limits practice (Adkins 2003). People acting within the field produce effects on it and are important in influencing the future of the field.

The field and the relationships that exist between individuals within the field provides focus and context to studies exploring the practice of individuals or groups; what is possible or acceptable in one field may be impossible or unacceptable in another (Grenfell and James 2004; Rhynas 2005). Fields are dynamic and thus the use of the field as a concept both encourages and requires a description of activities that make reference to the history of the field and to the time of the enquiry (Grenfell and James 2004; Thomson 2008).

Bourdieu likened a field to a game which has specific but not necessarily explicit rules (Bourdieu and Wacquant 1992). He described how new 'players' or individuals entering a field must learn these rules. The practices of individuals depend on their position within

the field and their position depends on the capital that they bring. The primary aim of players in the field is to attain or transform their capital and thus capital and the field are also interrelated; capital both shapes the field and can be attained from the field.

3.1.3 Capital

The concept of capital is used to represent the resources that are at the disposal of an individual or group (Lessard et al. 2010). Capital ultimately represents power which can be used to alter an individual's place in the field or social world they inhabit; those who bring or acquire capital are more successful than those who do not (Bourdieu 1986).

Bourdieu likened a field without capital to a game of chance: in such a game everyone is equally likely to win or succeed. As this is rarely the case in practice, capital introduces order or regularity to a field (Bourdieu 1986). The distribution of capital at a particular time brings structure to the field and governs how the field works, determining whether those who occupy a field will be successful in their practices (Bourdieu and Wacquant 1992; Houston 2002).

Bourdieu referred to three main types of capital: economic, cultural and social. Any of these forms of capital become symbolic capital when they confer prestige on the owner (Bourdieu 1977).

3.1.3.1 Economic Capital

Economic capital is represented by financial resources such as money or possessions or attributes that can be quickly and directly converted into money. Bourdieu devoted little time to explaining economic capital beyond criticising sociologists who did not look outside the monetary value of practices when trying to explain social life (Bourdieu 1986). However, he did argue that the exchange of economic capital by, for example, buying or selling goods, is transparent and has no intrinsic value other than being a means to an

end (Moore 2008). He also considered that cultural and social capital could be converted into economic capital (Bourdieu 1986).

3.1.3.2 Cultural Capital

Bourdieu developed the concept of cultural capital when trying to explain differences in the educational attainment of children from different social classes. Cultural capital refers to knowledge or skills that individuals possess. The cultural capital that is accrued from these knowledge and skills may be embodied, objectified or institutionalised (Bourdieu 1986).

In the embodied state, an individual acquires the knowledge and skills that may be used as cultural capital deliberately and at some personal cost in terms of time. Bourdieu likened the development of the embodied state of cultural capital to *'the acquisition of a muscular physique or a suntan, it cannot be done at second hand'* (Bourdieu 1986 p.49). Cultural capital is embodied only after diligent study and with the passage of time, such that it becomes part of an individual's habitus. Thus it cannot be bought, exchanged or endowed, and it dies with the possessor.

The objectified state of cultural capital refers to tangible and material objects such as paintings, books or music that are acquired or owned for their cultural meaning. Whilst such possessions could represent economic capital, it is the meaning of the objects to the individual that confers cultural capital (Bourdieu 1986).

Unlike the embodied and objectified states, the institutionalised state of cultural capital is conferred upon an individual in the form of, for example, academic qualifications or awards. In this state cultural capital permits the acquisition of economic capital by, for instance, permitting the owner to obtain more highly paid work (Bourdieu 1986).

3.1.3.3 Social Capital

Bourdieu described social capital as:

The sum of resources, actual or virtual, that accrue to an individual or group by virtue of possessing a durable network of more or less institutionalised relationships of mutual acquaintance and recognition.

Bourdieu and Wacquant (1992 p.119).

Social capital results from the development, whether deliberately or unconsciously, of social relationships that may be useful either at the particular juncture during which they are developed, or at some point in the future. Bourdieu posited that social capital is achieved through an exchange of material and non-material commodities and the continuation of social capital relies upon the continuation of exchanges, which usually requires individuals to invest time or effort (Bourdieu 1986). The amount of social capital an individual possesses depends upon the number of groups he or she belongs to, and to the economic, cultural and symbolic capital those groups enjoy.

3.1.4 *The interrelationship between habitus, capital and field*

As has already been alluded to, rather than existing in isolation, the three concepts that make up Bourdieu's theory of practice actually interrelate. This relationship was delineated by Bourdieu (1984 p.101) thus:

$[(\text{Habitus})(\text{Capital})] + \text{Field} = \text{Practice}$

Bourdieu (1984) considered that habitus and capital are directly related. Habitus regulates how hard individuals strive for capital and, in its embodied state, cultural capital becomes part of an individual's habitus: the knowledge and skills that an individual acquires help to shape their values and dispositions. The field controls both habitus and capital, but the capital or resources owned by individuals who form part of the field also

helps to structure the field and determine its success. In Box 1 I have provided a fictitious narrative to help explain how each of the concepts differs from each other and how they interact with each other. To facilitate understanding I have deliberately simplified the account. Whilst I have referred only to two fields and to limited forms of capital, in reality practice is influenced by many overlapping fields in which the individuals have differing values and beliefs (habitus) and bring and acquire various forms of capital.

Changes in the 'field' of academia have resulted in the cost of attending university to increase substantially. Within the field there is a group of academics who individually believe that education should be available to the academically gifted regardless of their ability to pay: this belief forms part of their personal 'habitus' or value system. A chance discussion at a networking event leads the academics to come together to form a charitable foundation that will provide bursaries for undergraduates. They consider that this will ensure the future success of the field, as the most academically able students will be able to attend university and may subsequently chose to have an academic career themselves.

Whilst setting up the charity it became apparent that, although each academic valued education, there were subtle differences in their other beliefs and dispositions. Through a process of, often unconscious negotiation that took these differing values into account, an ethos was developed that guides the way that the charity awards funding. This ethos represents both the collective habitus of the academics and the 'organisational habitus' of the charity, which is now, itself, a field.

Simon is an A level student whose parents instilled in him the importance of education. His habitus, or belief system, means that he wants to go to university. However, his parents are retired and cannot afford to pay the tuition and living costs; they lack the economic capital necessary for Simon to attend university. Because Simon strongly believes that a university education will help his future career he has worked very hard and achieved excellent grades in his modular courses. He is thus eligible to apply to the charity for funding. Hence, although his family lacks economic capital, Simon was able to draw upon cultural capital (his good educational grades) to attend university.

Box 1: Narrative account of habitus, capital and the field

Having provided an overview of Bourdieu's theory of practice, in the following section I discuss the way that the theory has been used in practice.

3.1.5 Applications of Bourdieu's theory of practice in the health literature

To encourage the use of his theory across disciplines Bourdieu deliberately avoided attaching himself to a specific academic field (Lessard 2010). Bourdieu's theory, whilst perhaps not as widely used in healthcare as appears to be the case in fields such as education, has been successfully used to explore healthcare practices.

Authors applying Bourdieu's theory of practice to healthcare often use one or perhaps two of the concepts, with capital being used more frequently than habitus or field. For example, Morgan et al. (2011) used the concepts of capital and field to highlight that the capital acquired by a professional who undertakes translational research may vary according to the field of practice. In their study, the symbolic capital derived from translational research was more desirable to clinical scientists than to basic scientists who considered translational research 'high risk' in terms of its potential to confer prestige.

Using a different form of capital, Stephens (2008) explored the influence of social capital on health inequalities. She considered that Bourdieu's interpretation of social capital helped to explain how societal groups maintain their status and resources. Although she only considered social capital, in her discussion she stressed the need to explore this within the broader social context, highlighting the importance of additionally considering concepts such as the field and economic capital.

Despite convincing arguments for the applicability of Bourdieu's theory to healthcare (Rhynas 2005; Lessard et al. 2010), relatively few papers have applied all three concepts to their data. Nevertheless, within this body of work, Bourdieu's theory of practice has been used to explore health related activities from a diverse range of stakeholders including the general public, patients, and healthcare providers or organisations. Dixon-Woods et al. (2006) used Bourdieu's theory of practice to analyse the accounts of women

who had consented to surgery. They reported that women viewed the educational qualifications and knowledge that surgeons had acquired as affording them significant status and power. The women's values disposed them to feel morally and socially obliged not to question their surgeon and to provide consent quickly to avoid wasting the limited resources of the health service. Application of Bourdieu's theory helped to highlight that the notion of choice in surgery was, to a large extent, circumscribed by 'rules of the field'. When coupled with the habitus of women and the unequal distribution of capital, patients consented to surgery they later wished they had refused (Dixon-Woods et al. 2006).

In their study of patient and doctor accounts of the removal of patients from a general practice list, Stokes et al. (2006) suggested that the dispositions of doctors and patients permitted each a 'feel for the game'. When doctors considered patients' values to be discordant to those that they expected in the field of healthcare they deemed their practices to be unacceptable. The same was true with regards to patients' views of doctors' values. When either party considered that these social norms had been breached the social realities of the field were altered and the relationship was undermined. Accompanied by disparity in the capital or power each possessed, this discordance contributed to a breakdown in the harmonious relationship that both patients and doctors desired. In such situations doctors considered they had no choice but to remove the patient from their practice list (Stokes et al. 2006).

Lunnay et al. (2011) applied the theory of practice to a study in which interviews were used to investigate why 14-17 year old Australian females drink alcohol. These young people explained their drinking behaviours in relation to the field (their peer group). If their peers were drinking they also tended to drink, if their social group was not drinking

then they also abstained. In this way social drinking became part of these young women's dispositions. Drinking became a behaviour used to accrue symbolic capital or prestige within their peer group, although this was not a direct result of their drinking, rather of their behaviour in the social events in which alcohol was consumed.

One of the foundational precepts of Bourdieu's theory of practice is that social rules and personal choices and values should be explored in tandem (Bourdieu 1977). Bourdieu was also clear that simply asking individuals to explain their practices was inadequate, as '*all that is inscribed in the familiarity with the familiar environment [...] does not reflect on itself and excludes the questions of its own possibility*' (Bourdieu 1977 p.3). For these reasons gathering interview data alone, as was the case in the three studies presented above, may fail to reveal the complexities of practice.

Lee and Macdonald (2009) adopted an ethnographic approach to investigate rural young people's participation in physical activity. They discovered a lack of local provision for sports that were concordant with the gendered dispositions of young women (e.g. netball or riding rather than the 'male' sports such as football and cricket). This, along with familial perceptions of sport as a form of social capital and the availability of economic capital (i.e. having sufficient money to be able to attend riding/dance classes) were important to their practice. The authors considered that the use of ethnographic methods and all three concepts that comprise the theory of practice allowed them to widen understanding of this area from the epidemiological approaches that had been used previously.

In her ethnographic study of the pain assessment practices of nurses in two postoperative units in the USA, Lauzon Clabo (2008) used Bourdieu's theory of practice to frame data collection and analysis. She adopted a three-phased approach to data collection in which

participant observation was used to map social context and understand the routines and general practices of the units. Interviews and observation of nurses' practices were then used to understand their pain assessment practices. Finally focus groups were employed to help understand how the social context influenced pain assessment practices. She found that nurses within each unit demonstrated similar practices to each other but markedly different practices to those on the other unit. She suggested that pain assessment practices were influenced not so much by the individual beliefs of the nurses, but by a 'unit habitus' that related to the specific field of practice that was dominant in each unit at the time. The differences in sources of social capital (on one unit this was deemed to be colleagues and managers, whilst on the other it was patients and colleagues) helped to explain the differences in the approach to pain assessment adopted by nurses on the two units. Lauzon Clabo (2008) considered that the use of ethnographic methods and identifying the importance of the field and social capital in understanding nurses' pain assessment practices helped to explain why previous interventions aimed at improving pain assessment practices had been of limited success.

3.1.6 Criticisms and limitations of Bourdieu's theory of practice

In the previous section the utility of Bourdieu's (1977) theory of practice in explaining the practices of professionals, patients and the public in the healthcare field was demonstrated. Authors of the empirical studies commented that the theory provided a useful lens through which to investigate the practices of groups of individuals by offering a broad and comprehensive framework with which to explore data (Lessard et al. 2010; Lunnay et al. 2011). Whilst the theory has been deemed useful, it has also been the subject of critique (see for example King 2000; Jenkins 2002). Although these appraisals do not directly discuss the application of Bourdieu's theory to healthcare, the criticisms are relevant to this field.

One criticism levelled at Bourdieu's theory is that it places the influence of gender, sexuality and race as of lower import to an individual's practice than that of social class, and thus fails to take account of all the factors that may be relevant (Lovell 2000).

Furthermore, although Bourdieu developed the notion of habitus to resolve the subject-object dualism, some have argued that, through this concept, he actually relapses into the objectivism he hoped to avoid. Bourdieu's assertion that habitus results in agents behaving in an unknowing manner and that their practices are guided by their previous experiences actually neglects the potential for individuals to understand their own practices (Jenkins 1982; King 2000). Thus, in Bourdieu's model, an individual's habitus would prevent them transforming their practice or breaking out of old moulds into new ways of behaving (Reay 2004).

It seems unlikely that Bourdieu intended habitus to restrict the theory in such a way. In Outline of a Theory of Practice he writes:

It is, of course, never ruled out that the responses of the habitus may be accompanied by a strategic calculation (Bourdieu 1977 p.76)

Whilst the criticisms that have been described are valid, Bourdieu was clear that his theories and concepts should not be used inflexibly, rather that they be viewed as 'thinking tools' that could be transformed and rethought during their application (Bourdieu and Wacquant 1992). With this knowledge, the aforementioned criticisms serve to encourage prudence to those making use of habitus or considering the influence of sociodemographic characteristics in their empirical studies. However, they should not prohibit use of the theory.

During data analysis it seemed that an additional theory, Titmuss' (1970) The Gift Relationship, was also relevant to understanding participation in paediatric RCTs. I will

discuss why I considered this theory to be useful in the concluding section of this chapter.

In the following section I describe Titmuss' theory before discussing the way in which it has been used to explain healthcare practices.

3.2 Titmuss' The Gift Relationship

Ideas of gift exchange have long preoccupied anthropologists. Writing in the 1920s Malinowski explored the social lives of the inhabitants of the Trobriand Islands and highlighted the '*general importance of give and take to the social fabric*' of their society (Malinowski [1922] 1966 p.194). In his book, 'The Gift' Mauss similarly describes how social life is underpinned by three obligations: to give, to receive and to reciprocate (Mauss [1950] 1990). He argues that, at first glance, this giving and receiving appears to be conducted in a disinterested and apparently free way in the form of a 'gift'. However, with closer study it becomes clear that the gift forms part of a contract that will be repaid in some form at some point in the future.

Titmuss (1970) used many of the concepts described by these anthropologists to try to understand individuals' '*regard or disregard for others*' (p.11) and the relevance of the social contract over the economic contract for society. To explore these ideas he examined the motivations of blood donors in (predominantly) two countries, the USA and the UK, which at that time had differing blood collection practices.

Using publically available data relating to systems and methods of blood donation Titmuss constructed eight donor typologies, whose motives ranged from purely financial, to purely altruistic. At the financial end of the scale was the 'paid donor' who sold his/her blood whenever they considered it expedient to do so. The 'professional donor' differed from the 'paid donor' in that they sold blood on a regular basis, using the revenue as a source of income. The 'paid-induced voluntary donor' donated blood due to pressure at

his place of work or from his community. Although he received payment for this donation, the amount received covered only the costs incurred by donating. The 'responsibility fee donor' gave blood in direct return for blood that they or a relative had been 'lent' by a hospital during a period of ill health. This donation was not voluntary. Rather it formed part of the agreement through which the hospital provided blood when it was needed; to fail to repay this with a donation would incur substantial financial costs. The 'family credit donor' donated blood on a regular basis (perhaps once a year) and in return was 'insured' against their blood needs for the forthcoming year. Titmuss did not consider this donation voluntary either because it formed part of a formal 'credit' plan. The 'captive voluntary donor' donated blood in response to requests by those in authority and may or may not have received financial reward for their donation. For example, military personnel or prisoners were encouraged to donate blood and did so in the hope of accruing social standing or good favour within their community. The 'fringe benefit voluntary donor' gave blood to receive non-monetary rewards such as time off work on full pay or free meals after donating. Finally the 'voluntary community donor' was, Titmuss argued, the closest typology to the concept of a *'free human gift'* (Titmuss 1970 p.88). They were not induced to donate blood by monetary or other tangible rewards, or by concerns about penalties for failing to donate. Rather they gave blood through their own choice and out of concern for others in society.

In addition to the typologies he developed using pre-existing data, Titmuss also gathered his own empirical survey data regarding UK donors' motivations for giving blood. He grouped the responses to a question that asked participants to explain why they first decided to become a blood donor into thirteen categories. These categories included a

range of motivations ranging from altruism, reciprocity, and an understanding of the importance of the need for blood, to personal benefit.

Titmuss suggested that, although altruism featured strongly in the motivations of UK donors, this was underpinned by *'some sense of obligation, approval, and interest; some feeling of 'inclusion' in society; some awareness of the need and the purpose of the gift'* (Titmuss 1970 p.238). In this way he considered that a practice that could otherwise be viewed as purely altruistic¹⁰ was actually influenced by a social contract. He argued that blood donation represented a moral transaction that stimulated and perpetuated relationships between individuals and groups. He likened blood donation to gift exchange, which he considered was an integral part of society and stemmed from a variety of motivations:

to express affection, regard or loyalty; to unify the group, to bind the generations; to fulfil a contractual set of obligations and rights, to function as acts of penitence, shame or degradation, and to symbolize many other human sentiments

Titmuss (1970 p.72)

He suggested that any episode of gift exchange was characterised by aspects of a moral code, and that blood donation, as gift exchange, was informed by elements of generosity, self interest, spontaneity and compulsion.

Using the empirical data and data relating to the safety, costs, usage and wastage of donated blood in these countries, Titmuss also proposed that models of blood donation that relied upon voluntary contributions were more safe and efficient than those which relied on paid donations. He thus concluded that, in such a context, the social contract was superior to the economic contract.

¹⁰ If the definition of 'pure' altruism is taken to be *complete* disinterestedness and selflessness (Titmuss 1970 p.238).

3.2.1 Application of Titmuss' The Gift Relationship in the health literature

Titmuss' work has predominantly been applied to studies exploring blood or organ donation practices. Healy (2000) described how blood collection practices had an important role to play in influencing donation rates and donor profiles. He attempted to replicate the essence of Titmuss' study and explored cross-national practices of blood donation in EU countries, modelling factors that might influence blood donation practices. He found that donors from countries that targeted groups in which volunteering was rated as a valuable characteristic (for example church groups) were more likely to be regular donors. He considered that this corroborated Titmuss' findings, and stressed the need to consider the social contract in altruistic and self-interested practices. Morgan et al. (2008) explored the views of Black British Caribbean people on registering as a kidney donor. Their study participants acknowledged the importance of the gift of donation, but not feeling part of the wider society and a lack of trust in doctors and the medical system were more relevant to their perceptions of, and reluctance to agree to, organ donation. Thus the findings of both Morgan et al. (2008) and Healy (2000) highlight the relevance not just of altruism, but also of social cohesion in practices that have often been described in predominantly altruistic terms.

More recently a body of work has used Titmuss' (1970) *The Gift Relationship* to explore the donation of human tissue for use in medical research, particularly to the biobanks that store and manage population level quantities of samples. Titmuss developed his theory in the 1960s, at a time when biobanks had not been conceived. However, both practices involve the donation of samples, often blood, to an unknown recipient in the hope of doing good. These similarities thus make this theory relevant to biobanking (Tutton 2002; Busby 2006). In this context the gift relationship has been used to argue for the importance of voluntary donations to biobanks (Yee 2009), to describe the behaviour

of individuals who donate to such schemes (Hoeyer 2010), and to represent the relationship of the sample to the giver and receiver when it is donated to the biobank (MRC 2001).

Although Titmuss' work has been used to investigate a variety of healthcare practices, Busby and Martin (2006) argue that not all studies make full use of the theory; concepts of social contract and reciprocity are often overlooked in favour of a rather simplistic reference to the importance of altruism. Using Titmuss' theory in this one-dimensional manner raises concerns about the exploitation of research participants. As I discussed in the previous chapter, individuals often devote considerable time and resources under a societal benefit model of participation but, in doing so, enable companies or individuals who use the samples to accrue substantial financial reward (Waldby 2002; Stones and McMillan 2010; Tutton and Prainsack 2011). Voo (2011) considers it exploitative to cite Titmuss' work as reason not to use material rewards to incentivise the public to provide samples for biobanks. He argues that the gift relationship should be interpreted as a framework that allows and encourages multiple reasons for people to donate samples, as to do otherwise constrains their ability to act in their own best interests. Oakley (1996) has also raised concerns over the simplistic use of Titmuss' theory to authenticate the blanket consent for donated samples to be used however the researchers, as custodians of the samples, deem suitable. She argues for the donor to be able to exercise control over how their sample is used.

In light of the calls for a revisioning of the way that Titmuss' theory was often used in healthcare prior to the middle of the 2000s, a growing number of studies have adopted a more complete approach to using the concepts to consider participation in biobank research. Hoeyer (2010) synthesised literature looking at trends in the public's views

about informed consent and desire for feedback regarding the research findings that result from studies using samples donated to biobanks. She found that, although the types of samples gathered and the studies conducted by the biobanks included in her synthesis were diverse, reciprocity and social cohesion were important themes for participants; many considered it was their duty and part of community living to participate in this way.

Morrell et al. (2011) conducted a qualitative study of patients who had donated their tumour tissue to a tumour bank. Participants explained that they were happy to donate their tumour tissue for research because, in doing so, they might help others. Morrell et al. (2011) considered that the concepts of altruism and social exchange resonated with their results. However, unlike the blood donors in Titmuss' theory, for these individuals there was no intentionality to their participation. They did not actively seek to help, but were happy to do so when they were asked (Morrell et al. 2011).

Dixon-Woods et al. (2008) explored why parents of children with cancer (and the children themselves where appropriate) donated tumour tissue to biobanks. In their semi-structured interviews they found that the enthusiasm of those who donated tissue varied from those who 'didn't mind' to those who said that they were desperate to help. Parents and children agreed to take part both to help others and because they felt part of a community that was united in pursuit of a common goal. However, only half of those interviewed felt comfortable with the use of the word 'gift' to describe the donation that they had made. The others considered that the term trivialised the donation and was frivolous and patronising: they did not feel that they had given a gift, rather that they had assisted with research (Dixon-Woods et al. 2008). This contrasts with Fisher (2008), a donor to a biobank herself, who felt that the term gift was appropriate as it highlighted

the attachment or 'social bond' that she considered her donation created between her and the researchers.

Other authors have used Titmuss' theory to explore the motivations of individuals who take part in clinical trials that involve a more continuous and personal relationship than is often required when donating tissue to a biobank. Locock and Smith (2011) explored patients' reasons for choosing whether or not to take part in clinical trials of interventions for a variety of different conditions. Unlike other studies, the authors included patients who chose not to take part or who withdrew from trials as well as those who agreed and completed their participation. They found that personal benefit and societal benefit were relevant to participation: patients hoped for faster access to treatments but also wanted to contribute to society (Locock and Smith 2011). These findings are similar to those of Morris and Schneider (2010) who explored volunteers' experiences of participating in research on novel diagnostic technology for breast cancer. Despite participants in this study not receiving any personal benefit from participation, their altruistic motivations could be categorised according to whether they participated in the hope of helping a family member or friend, or whether they saw participation as a civic duty.

3.2.2 Criticisms and limitations of Titmuss' The Gift Relationship

One of the major criticisms of Titmuss' work is that his method of collecting data lacked rigour and thus the authenticity of his findings is limited (Rapport and Maggs 2002). Due to the rapid advances in healthcare and changes to wider society, others have questioned the utility of a theory that was developed in post war Britain to 21st century healthcare (Farrell 2006). Perhaps the most prevailing criticism of Titmuss' theory applies to the way it is used. As I described in the previous section, a theory that was developed to explain social policy and the organisation of the health services has often been used to describe

individual altruism, resulting in a distorted and simplistic interpretation which overlooks the role of reciprocity and social cohesion in favour of a celebration of individual altruism (Busby 2006). Despite these limitations several authors have successfully used this work to explore the practice of organ and blood donors, as well as those who participate in research. In this thesis I have attempted to ensure that the theory has been used to explore the social organisation of the trials and considered notions of reciprocity as well as altruism within the data.

3.3 Conclusion

Bourdieu's theory of practice was chosen as the theoretical framework for this thesis because I considered it would encourage an alternative viewpoint from which to explore participation in paediatric RCTs from those that have predominantly been used to date. Although some studies have attempted to 'profile' the characteristics of those who take part in research and there is a limited literature exploring participation using psychological theory, few studies have considered participation using sociological theory. Where social theory has been used to investigate prosocial healthcare activities, in, for example, studies of practices including women's consenting to surgery and young people's participation in sports or underage drinking demonstrate, the utility of the theory in advancing knowledge within these health related fields is evident. This is particularly the case when used alongside an ethnographic approach to data collection.

As I will go on to show in the results chapters, the concepts utilised by Titmuss (the social contract, altruism and reciprocity) and the donor typologies that he developed resonated with the data I had collected. Although these data relate to the factors that influence research participation rather than to blood donation as was the case in Titmuss' study, this resonance is perhaps unsurprising. Titmuss (1970) explained that, whilst he used

blood donation to explore these issues, he could equally have chosen *'the giving role of the patient as 'teaching material', and as research material for experimentation and the testing of new drugs and other diagnostic therapeutic measures'* (p.213).

The societal benefit and personal benefit models that are often discussed in relation to participation in research are also evident in the two theories. In *Outline of a Theory of Practice*, Bourdieu (1977) described the practices of gift exchange he observed between people living in Kabylia, Algeria where he conducted his first major research. He used his theory to explore these practices and argued that the temporal structure of gift exchange differentiates itself from the more simplistic 'swapping'. He considered that gift exchange both creates and is underpinned by social capital. In line with his perception of capital as a tool that is used to advance one's place in society, it is evident that personal benefit, including personal indebtedness and reciprocity, sits at the heart of his analysis of exchange practices.

Titmuss (1970) also considered the notion of exchange but took a totally different view. For him, the benefits that accrue from exchange practices centre on a societal benefit model. He argued that individuals donated blood because of a sense of inclusion in society and to repay the care they had received or might receive in the future. Although he acknowledged the existence of personal benefit models in blood donation practices, he viewed them as much less desirable. By representing the two ends of the societal versus personal benefit debate, the differing viewpoints from which Titmuss and Bourdieu explore participatory practices seemed to offer useful lenses through which to consider participation in paediatric RCTs. In particular they will be used to consider whether either model of participation is preferable to parents and staff, and whether either model is superior in facilitating recruitment, adherence and retention.

In the following chapter I present the methods that were used to collect the data for this thesis.

Chapter 4: Methods

In this chapter I present the methods used to collect data for this study. An ethnographic approach was taken to data collection, with two RCTs being used as case studies for this research.¹¹ I begin by providing a rationale for the approach, before discussing the tools that were used to collect the data: participant observation, semi-structured interviews with parents and staff, and documentary analysis. I go on to explain how the data were analysed. Finally I describe some of the issues that I faced during data collection and analysis and consider how my previous experiences of the fieldwork setting may have influenced the process of collecting and analysing data.

4.1 Rationale for the ethnographic approach

In considering the approach that would be taken for this study I considered the strengths and limitations of the methods that others have used to explore participation in prosocial healthcare activities. As described in Chapter 1, the literature exploring participation in paediatric RCTs has primarily taken one of two approaches. One body of literature comprises studies that either model predictors of participation using sociodemographic factors or psychological characteristics (see for example Allehoff et al. 1988; Tait et al. 1998; Dunngalvin et al. 2009), or employ forced choice questionnaires to explore parental attitudes to research participation (see for example Dias et al. 2005; Jay et al. 2007; Sammons et al. 2007). Such approaches limit understanding of the issues that those who are directly involved consider to be important. For this reason an increasing number of studies have adopted qualitative methods, primarily interviewing parents about their experiences of deciding whether or not to enrol their children in research (see for example Glogowska et al. 2001; Snowdon et al. 2007; Ward 2009). More recently a small

¹¹ These case studies are described in detail in the following chapter.

number of papers have been published in which the views of children and/or staff are included and in which the interaction between parents and staff is examined (see for example Snowdon 2005; Shilling et al. 2011).

The findings of the current literature on participation in paediatric trials highlight that a variety of factors pertaining to the family, the trial and the trial staff are relevant to participation. However, to date, the methods used to explore participation in paediatric trials have resulted in a somewhat restricted understanding. Focusing on the views and experiences of parents, trial staff, the trial environment and even the interaction between the parents and staff, has allowed trials to be viewed as isolated entities in which participation occurs independently of the wider context. The findings of the literature exploring prosocial healthcare activities more generally suggest that the wider context has a role to play in participation, and this is also evident when synthesising the findings of the current paediatric trials literature. In designing this study I considered that a method that promoted understanding of both trial specific factors and the wider context was desirable. Thus I deemed that an ethnographic approach would be the most appropriate.

Ethnography is a form of social research that takes as its starting point the view that individuals experience the world through a framework of symbols and cultural meanings (Taylor 2002). Although, historically, ethnographers tended to travel to distant and exotic locations to study unfamiliar cultures, increasingly ethnography is being used to shed light on the more 'familiar' (Taylor 2002). Certainly the approach is rising in popularity in health related fields (Pope 2005).

The aim of ethnographic research is to understand the way a particular group of people behave and interact and, importantly, the significance of these behaviours and

interactions within the setting in which they usually occur (Hammersley and Atkinson 1995; Fielding 2001; Taylor 2002). Ethnography is characterised by ‘thick description’ (Geertz 1973), which relates not only to the collection of detailed data, but to the collection of data in which the nuances of behaviours, given the context in which they occur, are understood (Wolcott 2001). This is frequently explained with reference to Geertz’s (1973) twitch-wink discussion: differentiating the closing of an eye as a twitch or a wink depends upon understanding the situation in which it occurs, the meaning to the individual and, furthermore, the meaning to those who witness the eye closing.

Ethnography is also characterised by the methods used to collect data: participant observation; interviews; and documentary analysis (Hammersley and Atkinson 1995; Wolcott 2001). In utilising participant observation alongside interviews and documentary analysis, ethnography permits an understanding of what individuals do, as well as what they say they do, and of the way in which the location they inhabit influences their actions (Atkinson and Pugsley 2005; Reeves et al. 2008).

I considered that an ethnographic approach to data collection would help to overcome the limitations of the current literature on paediatric trial participation and, therefore, might extend the existing knowledge of this field. Some argue that for a study to be truly ethnographic a large proportion of data should be collected using participant observation (Bloor 2001). In the RCTs that were used as case studies for this research much of the research participation was carried out by parents in their day-to-day lives, usually at home, but certainly away from the clinical trials unit from which the trials were run. As it was not practical to conduct participant observation in these settings data from interviews with parents and staff made a substantial contribution to my findings. Thus for

the purpose of this thesis I will refer to the use of an ethnographic approach rather than define the study as an ethnography *per se*.

In the following sections I describe the methods used to collect and analyse data, but first I discuss the process of gaining approval to conduct the study.

4.2 Gaining approval to conduct the study

Prior to starting data collection ethical approval was obtained from the Proportionate Review Subcommittee of the Kings College London Research Ethics Committee on 23 February 2010 (Ref: 10/H0808/26 see Appendix 4) and the Research and Development (R&D) department of Guys and St Thomas' NHS Foundation Trust granted permission on the same date (Ref: RJI 10/N043 see Appendix 5).

Problems gaining access to conduct research regarding participation in RCTs are not uncommon (de Salis et al. 2008). Shilling et al. (2011) described difficulties gaining permissions from the ethics and R&D departments due to uncertainty as to whether their study was part of, or separate to, the trials it was aiming to investigate. Snowdon (2005) described similar difficulties and also discussed how the unpredictable nature of trials meant that one of the proposed case study trials was discontinued prior to her study beginning. Furthermore, she highlighted the difficulties she faced in gaining the agreement of the trial investigators to collaborate with her study.

Whilst I had no difficulty gaining the relevant ethical and R&D approvals, gaining access to the trials that would be used as case studies for the research was more difficult, even though I had worked on one of the trials prior to beginning my PhD and the trials' Principal Investigator (PI) was also one of my PhD supervisors.

Although we had informally discussed the study, the process of gaining access to conduct the study with the two RCTs (henceforth referred to by their acronyms: LEAP and EAT¹²) began with a conversation with the trials' PI.¹³ He explained to me that he thought it would be possible to include both trials but that it was necessary to gain the consent of the organisations that funded the trials and, in the case of EAT, the steering committee. I asked how to go about this and he told me that he would make an approach on my behalf, but that he felt that the timing of the request was important with regards to gaining agreement. He was in negotiation with the funders/steering committees of both trials regarding other studies that he wished to run alongside the main RCTs. Additionally recruitment to EAT was slow, and there were questions as to whether the trial would be able to continue. For these reasons he wanted to wait until he considered the time was right to mention the study.

Knowing how busy the PI was, I periodically asked whether the 'right time' was approaching. Although he voiced support for the study, I felt that, in his decisions about the timing of the approach, other studies, which were perhaps more in line with his area of interest, took priority over mine. After some months, and once approval for other studies had been granted, he discussed the study with the LEAP funders. There was a short delay in gaining their agreement due to uncertainty as to who within the organisation could give approval and also due to concerns about the effect that the additional burden of the study would have on parents' participation in LEAP itself. After understanding that proportionately small numbers of parents would be included in the study they gave permission and I was pleased that I would now be able to start collecting data. However, a further delay occurred when the staff involved in the day-to-day

¹² LEAP stands for Learning Early About Peanuts; EAT stands for Enquiring About Tolerance.

¹³ Both LEAP and EAT were investigator initiated trials and shared the same PI. The PI (along with other researchers) developed the concepts and applied, through a competitive process, for funding.

running of the trial decided that they should gain ethical approval from the ethics committee that had approved LEAP. After a discussion with the chair of that committee it was agreed that approval was not needed as this had already been granted by another committee, but that the staff should submit a formal notification to their ethics committee that the study was to take place.

The PI approached the EAT funders and steering committee some time later, after he considered that their concerns about the slow recruitment were starting to lessen and once another 'add on' study had been approved. Once the approach was made to EAT, and perhaps because I had been conducting the study with LEAP for sometime without an obvious influence on participation in that trial, the agreement to conduct the study was given readily. The staff also provided the same notification to the ethics committee that approved EAT as had been provided by LEAP.

In the following sections I describe how data were collected using each of the three ethnographic methods: participant observation; interviews; and documentary analysis.

4.3 Participant observation

Participant observation is a useful tool for understanding the practices of individuals as they occur within their natural setting and, in particular, for understanding the interactions that take place between individuals or groups (Emerson et al. 2001). From May 2010 until June 2011 I conducted observation on the clinical trials unit from which the daily activities of LEAP and EAT took place. The initial focus of my observations was the LEAP staff as, for reasons mentioned earlier, I was not granted permission to conduct the study with EAT until January 2011.

4.3.1 Gaining access for observation

After obtaining the relevant permissions to conduct the study the PI suggested that I could have open access to the clinical trials unit. However, to ensure that the staff that I would be observing had the opportunity to decide whether or not to take part, I attended the end of a team meeting for each trial and briefly outlined the study. All staff were also given written information about the observation (Appendix 6) and asked to return a signed consent form if they were willing to take part.

In total 11 LEAP and six EAT staff who were involved in the day-to-day trial activities agreed to be observed. One LEAP staff member declined participation. This staff member told me directly that she would rather not take part in the observations. One EAT staff member was also excluded from the observations. This individual verbally agreed but, despite me asking on several occasions whether she had read the written information and would be willing to sign the consent form, she always replied that she hadn't had time but that it 'shouldn't be a problem'. After four similar conversations over the period of about six weeks I decided that perhaps she did not want to participate but felt uncomfortable telling me so. I thus decided not to pursue her participation. Activities that included the staff members who had not given written consent to be observed were not recorded unless I could record observations of other staff members without including their activities (e.g. in a team meeting where I could record all observations except conversations to which that staff member made a substantial contribution).

The focus of my observations was the way that staff facilitated participation in the trials and, in line with the ethical approval I had received to conduct the study, I did not seek the written consent of parents attending the clinical trials unit.

4.3.2 *Negotiating the participant role*

The role that is undertaken during data collection can influence the quality and depth of the data that are obtained (Knox 2005), but problems establishing a place in the field are not uncommon (see for example Spradley 1980; Emerson et al. 2001). I began by negotiating the role I would take with the staff who would be the focus of my fieldwork. I hoped to be as immersed in the daily activities of staff on the unit as possible as I believed this would increase the team's acceptance of me and potentially lead to more accurate data (Vidich 1955; Snow et al. 1986; Hammersley and Atkinson 1995). Although I hoped to negotiate a relatively embedded participant role, when I discussed this with senior members of the LEAP team they considered it would be 'cleaner' if I did not play an active part in their daily activities [personal communication 30th April 2010]. Consequently I had no specific role and spent a lot of time simply observing, although I did try to make myself generally useful by, for example, answering phones and doors if no one else was free, and assisting with measuring the length of the babies; a two person job.

I was initially disappointed with the lesser participant role and considered claims of participant observation would be disingenuous as my role more closely resembled an 'observer-as-participant' than the 'participant-as-observer' one I had hoped for (Gold 1958). However, Hammersley and Atkinson (1995) suggest that such a distinction is meaningless, particularly if the observer is familiar with the environment under study. As I will discuss in Section 4.9, I did have prior knowledge of the trials and clinical trials unit and although I considered trying to renegotiate my role to one that involved a greater degree of participation, after a few weeks I decided that the lesser degree of participation held advantages. I was already familiar with the setting from the viewpoint of a staff member and the less participatory role allowed me to reflect on how staff interacted families in a way that might not have been possible if I had been actively participating in

the day-to-day activities of the unit. Once the permission to begin observation with EAT staff was granted, I did not try to adapt my role. I will further explore how data collection was influenced by my role in Section 4.9.

4.3.3 Observing activities on the clinical trials unit

I attended the clinical trials unit regularly for thirteen months, from May 2010 until June 2011. During this time I observed LEAP and (from January 2011) EAT staff in their usual daily work activities: conducting scheduled and unscheduled trial visits with children and their parents; making and receiving telephone calls from potential and current participants; and attending team meetings. Each session of observation lasted between three and eight hours and I varied the days and times that I attended the unit to try and observe a broad spectrum of activities. In total I conducted 130 hours of observation.

When I first started observing, in an effort not to miss any 'vital' piece of information, I tried to listen and watch everything that was happening on the unit. After a few sessions I realised I was failing to achieve the depth of observations considered necessary in the ethnographic approach (Geertz 1973; Fielding 2001) and decided instead to focus on one particular event at a time. For example, I would either spend a set period of time observing telephone calls being made or I would observe a trial visit, which I would follow through from the time the child and family arrived until they left the unit.

To avoid copious note taking which would not only detract my attention from my observation but may have also made those I was observing feel self-conscious (Emerson et al. 1995), I used a small piece of paper, on which I jotted keywords to act as an aide memoir when I wrote up the observations. Wolfinger (2002) suggests two methods of note taking; the comprehensive method and the saliency method. I employed the comprehensive method of note taking described by systematically noting everything that

happened during the observation period. I considered this preferable to the saliency method, as I was less likely to omit information that I deemed 'irrelevant'. The comprehensive method should have reduced the subjectivity of my observations (Wolfinger 2002).

After I left the unit I typed up a full record of my observations starting from when I entered the unit and writing temporally in as much detail as possible. To maximise accuracy, I wrote the full field notes on the same day as I had conducted the observation. As well as describing the activities on the clinical trials unit, I also kept a diary in which I noted my thoughts and feelings of the observation, including reflections on how I considered my presence influenced the behaviour of staff members (Emerson 1987).

In the following sections I discuss the second data collection method, interviews, which I conducted with parents and with trial staff.

4.4 Parent interviews

In addition to observing what happened on the unit I also wanted to explore parents' views and experiences of their participation in the trials. Children took part in LEAP for five years and EAT for three years, but had only five (LEAP) and three (EAT) scheduled trial visits during this period. Thus most of the research participation was performed by parents and away from the unit. As I wanted to gain an understanding of the aspects of participation that occurred outside the unit setting, I considered that, as well as exploring parents' views of their participation in the trial, interviews would be a good means of uncovering 'at home' aspects of participation.

4.4.1 *Sampling*

Sampling of respondents for qualitative interviews can have a significant influence on the findings (Holstein and Gubrium 1995) and, as relatively little was known about the area of

study, I considered that maximum variation sampling would promote access to a wide range of views and experiences (Coyne 1997; Luborsky and Rubenstein 2001; Patton 2001). I began by inviting LEAP parents to take part in the study and, with one caveat, I decided that I would invite all parents who were participating or who had withdrawn from LEAP to take part in the study. I felt this would allow me to interview a more diverse group of parents than if I had simply approached those who attended the clinical trials unit for one of the trial visits.

The caveat to my inviting all LEAP parents to take part reflected concerns that had been expressed by the LEAP PI and funders (see Section 4.2) that participation in the study might influence parental willingness to continue their child's participation in LEAP. Given their concerns and my desire not to influence participation in the RCTs, I asked the LEAP team whether there were any parents who would not react well to receiving an invitation to take part in the study and who should be excluded. The LEAP team initially excluded 44 families who they felt had had 'problems' with participation. I was disappointed by this, as I believed that these families would provide important insights particularly as, despite staff views that the families had faced difficulties during their participation, they had continued to take part. I asked whether the team would consider the list again and outlined that it might be important to give these families the opportunity to participate in the study, particularly as the invitation stressed that they were under no obligation to take part. The staff reviewed the list again and ultimately 26 families did not receive an invitation to take part. Table 1 lists the reasons LEAP staff gave me for their exclusion.

Reason	Number
Contact and/or personal difficulties	11
Anxiety re LEAP participation, has discussed withdrawal	9
Parent occasionally challenging	3
Parent seriously ill	2
Child undergoing frequent hospital visits for unrelated condition	1

Table 1: Reasons parents were not invited to participate in the study

In total 609 parents whose children were still participating and all five parents who had withdrawn their children from LEAP were invited to take part in the study. The invitation took the form of a short, personally signed letter (Appendix 7), which accompanied the participant information sheet (Appendix 8) and was sent to the home addresses of LEAP parents between September and November 2010.

Eighty-one parents, one of whom had withdrawn her child from LEAP, responded positively to the invitation. Using maximum variation sampling I purposively sampled parents for a range of factors that, using the existing literature, I considered might influence experiences: gender; the randomisation arm; the geographical area that the children lived in; the length of time they had been participating; and the method of their recruitment. Although I would have liked to sample parents based on their ethnicity, this information was not captured in the databases that I was able to access. I felt uncomfortable about asking parents their ethnicity for the purpose of sampling, and thus ethnicity was not one of the characteristics that I used in my sampling frame.

Of the 81 parents who responded, four fathers personally replied to the initial letter. As it can be difficult to access fathers to take part in research (Costigan and Cox 2001) I was encouraged to receive these responses, but ideally wanted to increase this number. After

purposively sampling the mothers who had responded I considered I was likely to have more potential participants than would be needed to achieve data saturation¹⁴ (Guest et al. 2006; Bowen 2008). Consequently I asked any mother whom I thought I would not need to interview whether the father of her child might be interested in participating. One additional father was recruited this way. One mother replied on behalf of her and her husband and thus, in total, six LEAP fathers were interviewed.

I aimed to continue data collection until I considered that no new information was being obtained and, after twenty-eight interviews, I felt that the previous two interviews had not produced new information. I wondered whether I had reached data saturation and decided to conduct an additional three interviews to ascertain whether this was the case. As these interviews revealed no new information I considered data saturation had been achieved. However, as only one mother who had withdrawn from LEAP and only six fathers whose children were participating in LEAP were interviewed, I did not feel that data saturation had been reached for these groups. Because I had permission to approach parents only once I was unable to re-issue the invitation and thus to interview additional parents who fell within these categories.

The sampling strategy that I adopted for EAT varied slightly from that used for LEAP. One of my reasons for using two RCTs as case studies was that they were at different stages in their overall conduct: LEAP had finished recruiting and EAT was still recruiting participants.¹⁵ I anticipated that interviewing EAT parents would allow me to explore recruitment in a more robust manner than was the case for LEAP, as I would be able to

¹⁴ Data saturation is a notion that is commonly used in qualitative research with respect to the sampling of participants. Under this concept new participants are continually brought into a study until the researcher considers that no new data are being obtained, i.e. until the data from new participants serves only to replicate that which has already been gathered. This point is referred to as data saturation and, once this occurs, it is usual not to bring new participants into the study.

¹⁵ I will discuss the rationale for including both RCTs in greater detail in Chapter 5

interview parents close to the time that they made their decision and thus minimise the risk of retrospective bias. For this reason, rather than inviting all parents to take part, I chose to ask only those who had recently made a decision about whether or not to enrol their children in the trial.

In February 2011 letters were sent to all parents who had expressed an interest but ultimately declined participation in EAT between November 2010 and January 2011 (150 families in total). Six parents responded and all were interviewed.

As the EAT steering committee had similar concerns to the LEAP funders about whether participation in the study would negatively influence participation in their trial I asked EAT staff whether any parent whose child was participating in the trial should not be invited to take part in the study. They felt that none needed to be excluded. In March 2011, letters were sent to all parents who agreed to enrol their children in the trial and who had attended their first EAT visit between November 2010 and January 2011 (97 letters in total). I did not send letters to parents who had attended their first visit in February of that year as EAT staff had expressed concerns about overburdening parents in the first month of their participation. Thirty two parents who were participating in EAT agreed to be interviewed, and I used the same criteria as I applied to LEAP to decide which parents to interview. No fathers responded to my initial letter, although three mothers responded on behalf of themselves and their husbands. After 14 interviews I considered that data saturation had been reached but conducted another two interviews to confirm whether this was the case. After these 16 interviews I asked the mothers whom I did not need to interview whether their child's father would consider taking part. No additional fathers consented.

As a relatively small number of parents (17) had withdrawn from EAT since they began recruitment in 2009 and only one parent who had withdrawn her child from LEAP had agreed to take part in the study, I invited all parents who had withdrawn their children from EAT to take part, regardless of when this decision was made. At the end of February 2011 I sent letters to all but three parents who had withdrawn. One mother had withdrawn within a month of her child enrolling on EAT due to the sudden death of her husband and I did not feel it was appropriate to contact her, and two families had moved abroad and no forwarding address was available. Fourteen letters were sent and two mothers responded to my letter and were interviewed. Given the small number of parents who responded, data saturation was not reached in this group.

4.4.2 Conducting the interviews

I invited parents to choose a convenient time and place for their interview. All EAT parents and most LEAP parents chose to be interviewed at home. Two LEAP parents were interviewed in a meeting room at my workplace. One mother who had moved abroad but whose child was still participating in LEAP was interviewed by phone. Five parents (one father and four mothers) were interviewed at their places of work and one in a café close to his workplace. For most families only one parent was interviewed, but one couple whose son was participating in LEAP, three couples whose children were participating in EAT and one couple who declined participation in EAT were interviewed. The couples were given the option of being interviewed together or separately and all chose to be interviewed together.

At the start of the interview I confirmed whether the parents had read the written information sheet and summarised what participation in the study would involve. After answering any questions I obtained their written consent to participation. The interviews

took a semi-structured format as I considered this approach would allow the breadth and depth of detail that was desirable (Holstein and Gubrium 1995; Sherman Heyl 2001). I used a topic guide (Appendix 9) to steer the conversations towards certain areas, but within these areas tried to encourage the parent to discuss the topics they deemed most important. For example, sometimes parents would begin to tell me something but then stop and suggest that perhaps I would be asking them about that later. In such situations I invited parents to tell me whatever they wanted to and said that I would amend my questions accordingly.

The topic guide was designed using the current literature and information from my observations. The broad areas covered were: parents' previous knowledge or experience of research; their child's state of health when they heard about LEAP or EAT; their thoughts when they heard about the trials; how they had made their decision regarding participation; and how they found their ongoing participation. The initial topic guide was piloted on the first five LEAP parents to be interviewed and small amendments made, particularly to the ordering by which topics of interest were introduced, to try to facilitate parents' building of a story around their research participation.

Most interviews lasted about 45 minutes (range 22 minutes - 1 hour and 14 minutes). With permission all interviews were digitally recorded and I transcribed the recordings verbatim. Halcomb and Davidson (2006) discuss the notion of verbatim transcription and highlight that the term can be used to describe the reproduction of both speech and non-verbal cues. They consider that 'verbatim' transcription is influenced by the way in which the transcriber hears and perceives the speech. When transcribing the interviews I included all speech as it was uttered, including hesitations such as 'um' and 'ah.' I also noted some non-verbal cues, in particular long pauses, but when reflecting on this

transcription I realised that the recording of these non-verbal cues was not as rigorous as my recording of speech.

Parents completed a short demographic questionnaire at the end of the interview (Appendix 10). I made brief field notes during and after the interviews and these notes and the demographic details were attached to the verbatim transcripts of the recorded interviews for use during analysis.

4.5 Staff interviews

I had many informal conversations with staff during my observations on the clinical trials unit, but all staff who worked on LEAP and EAT during my fieldwork period were invited to participate in an interview. These interviews were used to seek clarification of the events that I had observed and to explore how staff viewed their role in facilitating participation in the trials. I was also able to gain a broader understanding of the challenges parents faced when they took part in the trials.¹⁶ I explained the purpose of these interviews at LEAP and EAT team meetings and staff were given written information to take away and consider before agreeing to participate (Appendix 11). All LEAP staff and all except one EAT staff member (the same staff member who did not participate in the observations) agreed to be interviewed (LEAP n=12, EAT n=9¹⁷). All staff provided written informed consent prior to their interview.

In addition to interviewing staff who were involved in the day-to-day conduct of LEAP and EAT, I also interviewed two individuals who worked for the organisation that funded and acted as sponsor for LEAP (the Immune Tolerance Network in the USA) and three

¹⁶ Or at least the challenges parents discussed with the staff.

¹⁷ More LEAP and EAT staff were interviewed than were observed as the PI had a limited role in the conducting the daily activities of the trials and thus was not observed. Additionally two new staff started on EAT at the very end of the observation period and, to give them time to adapt to their new role, I did not ask them to take part in the observations, but did ask them to take part in the interviews.

members of the EAT steering committee, including members of the funding body (the Food Standards Agency). The purpose of these interviews was to gain an understanding of the emphasis the funders of research and those who plan and guide research placed on the recruitment of children and their ongoing participation, and how they resourced these activities.

Staff interviews were semi structured and conducted using a topic guide (Appendix 12). The topic guide was designed using the literature and information from my observations and, as for the parent interviews, was used flexibly to promote an understanding of the issues that staff felt were important. I invited the staff to choose a convenient time and place to be interviewed. Most staff were interviewed in a quiet place in or around their workplace. One staff member who worked for the funders of LEAP, and one who sat on the EAT steering committee were interviewed by telephone.

I began interviewing staff about three months into my observation period with LEAP and about one month into my observation period with EAT. This allowed time for the staff and I to develop a rapport that I hoped would facilitate the interviews.¹⁸ Most interviews took about an hour (range 14 minutes - 1 hr and 40 minutes). With permission all interviews were digitally recorded and, as for the parent interviews, these recordings were transcribed verbatim. I also made notes of my impressions of the interviews, which were attached to the verbatim transcripts for use during analysis.

In the following section I describe the third source of data for the study: documents

¹⁸ During my observations of LEAP, I got to know EAT staff; hence I considered that less time was needed prior to the interviews.

4.6 Documentary analysis

Although participant observation and interviews were useful for understanding many aspects of participation in the trials, they were less suited to explore the ‘unobservable’ (MacDonald 2001) such as events that occurred outside the boundaries of the unit or before my observation period began. Documents can offer access to such data (Scott 1990) and also provide information about current events that may not be immediately obvious (Hammersley and Atkinson 1995). I therefore decided to include documents that were relevant to participation in the trials.

I decided *a priori* that I would ask parents to give examples of any documents they used to help them make choices about their child’s initial and continuing participation in LEAP and EAT, but few documents were obtained this way. When I asked parents to recall such documents all of them referred to the parent information sheet and some to the websites or newsletters that LEAP sent to participating parents. Only one mother, who chose not to take part in EAT, could recall any other documents she used. These were parenting books that discussed recommendations for feeding and weaning babies.

Burnham et al. (2004) explore the many difficulties facing researchers when trying to identify documentary sources and argue that the main problem is predominantly the range and diverse nature of potential documentary sources. They recommend designing a classification system to aid decisions about which sources are the most important and suggest a system employed by Lichtman and French (1978), in which sources are categorised as primary, secondary and tertiary. Although this classification was designed for historians I found the analogy helped me to consider the types of documents that might be useful. Table 2 (p.116) shows how I adapted the three categories for use in the study.

I discussed the documentary analysis element of the study with the LEAP and EAT staff. Together we created a list of documents that had been seen by parents including parent information sheets, newsletters and templates of letters that were sent to the GPs of children who were participating in the trials. As all scheduled correspondence between parents and the trials had to be approved by ethics committees, the staff checked back

Category	Types of document (Lichtmann and French 1978)	Types of document (As applied to this study)
Primary	Evidence that was part of a historical event	Documents produced by LEAP or EAT (e.g. parent information sheets, newsletters)
Secondary	Documents produced soon after a historical event	Documents that directly related to LEAP or EAT but not produced by the trials (e.g. content on parenting websites about the trials)
Tertiary	Material written long after a historical event to help with reconstruction	Documents relating indirectly to LEAP or EAT, e.g. media reports or government documents relating to research participation or food allergy.

Table 2: Classification system for documentary sources.

through the original application and any subsequent correspondence with their ethics committees and any documents that had been overlooked were added to the list. I also downloaded screenshots of the LEAP and EAT websites in June 2010 and revisited the sites in June 2011 to see whether any changes had been made. The full list of primary documents for LEAP and EAT is given in Appendix 13.

To gather secondary sources I used two Internet search engines (Google, and Lexis UK – an online resource that catalogues all English language newspapers) using the terms ‘LEAP peanut study’, and ‘EAT food allergy study’. The searches were first carried out in

June 2010 when I searched as far back as December 2006, the time that LEAP began recruitment. I repeated the search at the end of the fieldwork period in June 2011. The searches revealed links to online discussion forum websites and newspaper or magazine articles. Each of these was saved in paper form; screenshots of websites and printouts of newspaper articles were obtained. Where information was likely to evolve, e.g. online discussions, the pages were revisited on a three monthly basis until no new posts were added or until the fieldwork period finished in June 2011. A list of the secondary documents is given in Appendix 14.

I was less certain about how to obtain tertiary documents (those that did not directly mention the trials but may have been relevant). For the duration of the fieldwork period I opportunistically gathered stories from news websites and newspapers which made reference to participation in health research, particularly that involving children, or to food allergy. I also searched for government documents regarding research participation or food allergy. A full list of the included documents is provided in Appendix 15.

4.7 Data analysis

Data from the observations, interviews and documents were analysed alongside data collection using the principles of thematic analysis. This method is often poorly defined and frequently used as an umbrella term for modes of analysis in which patterns are identified in the data (such as grounded theory, or interpretative phenomenological analysis). Attride-Stirling (2001) considers that describing the method of analysing qualitative data as a thematic analysis results in an opaque analysis from which the reader is unable to gauge the authenticity of the findings. However, when the method of analysis is well defined, thematic analysis is a useful and flexible tool in its own right (Holstein and Gubrium 1995; Braun and Clarke 2006).

Braun and Clarke (2006) suggest six steps by which a thematic analysis may be conducted. These steps are summarised in Table 3, and in the following section I will attempt to overcome the problem of opacity by describing, in detail, how I analysed the data.

Phase
Familiarise yourself with the data
Generate initial codes
Search for themes
Review themes
Define and name themes
Produce the report

Table 3: Six steps of thematic analysis

I Initially took a ‘data-driven’ (Braun and Clarke 2006) approach to coding the raw data, allowing codes to develop from the texts rather than the underpinning theory or research questions. I began by analysing the interviews. Each transcript was read through carefully once and then re-read a second time. On the second occasion ‘codes’ were developed: small sections of data (e.g. a sentence or paragraph) were assigned a keyword that was representative of the essence of the text. NVivo 8 was used to assist with the management of the large amount of data. When all the data in the interview transcripts had been coded once the transcripts were revisited to establish whether early data fitted into later codes. Once I was satisfied that all data had been coded appropriately I employed the same method of coding to the field notes and then to the documents. Once data from all three methods of data collection had been coded, I re-read all the texts to consider whether any data should be added to additional codes.

I then looked for patterns within the codes and developed possible themes. I took a ‘theory driven’ (Braun and Clarke 2006) approach to this phase, using the three objectives

(the initial decision to take part, adherence to research procedures, and continuing participation in research) as well as the three facets of Bourdieu's (1977) theory of practice (habitus, capital and field) and the three concepts of Titmuss' (1970) gift relationship (altruism, reciprocity and social contract) to develop the themes.

The themes were then refined. I contemplated whether any themes could be fitted together, discarding those for which there was not enough supportive data. I re-read data extracts for each code and considered whether they formed a pattern. I also considered whether the themes accurately reflected the original data and identified any links that existed between them.

Ryan and Bernard (2003) consider that thematic analysis results in naive and simplistic readings of data. To overcome this problem Roulston (2001) suggests employing a reflexive approach to analysis. Throughout the process of data analysis I used memos (Emerson et al. 1995) to note my thoughts and ideas about the data. These memos were recorded on paper copies of the interview transcripts, field notes and documents, and were useful in the later stages of analysis, when developing themes and writing up the findings.

4.7.1 Reliability and validity

The means by which reliability and validity is assessed in qualitative research is the matter of some debate. Indeed, there is no consensus even as to the terms that should be used (Silverman 2006). I aimed to adopt a rigorous approach to data collection and analysis including the piloting of interview topic guides, the recording and verbatim transcription of interviews, adoption of a comprehensive approach to note taking in observations, and the keeping of a fieldwork diary. In the previous sections I have provided detailed

accounts of these methods to try and promote the credibility of my findings (Hammersley and Atkinson 1995; Attride-Stirling 2001).

Silverman (2006) suggests that respondent validation and triangulation can also be useful in producing a valid final account. Respondent validation is commonly used as a means of providing authenticity to the findings of qualitative studies, although this assumes that the findings are compatible with the views that those who take part have of themselves (Fielding 2001). As a means of validation I presented my work at conferences that were attended by HCPs who had experience of conducting research and discussed my findings with them. The findings seemed to resonate with their experiences.

I decided to collect data using participant observation, interviews and documents because I believed this would allow me to comprehensively explore participation in paediatric research. Whilst it was not the primary purpose, the use of more than one method of data collection also allowed triangulation of data (Hammersley and Atkinson 1995). Comparisons were made between the codes developed from each method of data collection and the extent to which there was concordance was explored. These findings are discussed in the results sections of this thesis.

4.8 Ethical challenges

In the following sections I discuss some of the ethical challenges I faced during data collection and analysis, including difficulties maintaining confidentiality and the acceptability of using data from online discussion forums.

4.8.1 *Anonymity and confidentiality*

In light of the emphasis placed on confidentiality in healthcare research, where reassurances about confidentiality are often made through guarantees of anonymity (Walford 2005), when I obtained informed consent for participation in the study I told

parents and staff that they would not be identifiable to anyone reading my final reports. As I came towards the end of my fieldwork I questioned how realistic this assurance had been.

The trigger for this came when a mother who had a unique and particularly distinctive story volunteered to be interviewed for the study. Whilst I considered she would offer important insights for this thesis, I knew that if I used quotes from her interview and contextualised these quotes, any staff reading my findings would be able to identify her. I discussed this with her during the interview and she was relatively unconcerned, agreeing that it was acceptable to use information that may identify her to the staff.

I then considered the issue of confidentiality and anonymity with other participants, and wondered, as others have done, whether my reassurances of anonymity were meaningless (see for example Van Den Hoonaard 2003; Walford 2005). To fully explore the data I needed to provide the context in which the study was carried out (Hammersley and Atkinson 1995). As I would be using data from 54 parents from a potential pool of about 2000 I felt I could maintain the anonymity of most parents except those with particularly distinctive stories. However, as LEAP and EAT only employed about twenty staff to work with parents and children I was concerned that anyone reading my findings who knew the teams that conducted LEAP and EAT would be able to identify individual staff members. I wondered whether it would be better not to name the trials or the hospital specifically, but decided that the context of the trials and the questions they were answering were essential to the thesis. As the trials were unique, at the time of my fieldwork there were no other interventional trials in the world that were employing similar designs to answer similar questions, withholding this information would be futile because the context of the trials would make them fully identifiable.

Whilst I did not consider my observations or the interviews held data that would cause offence to those who participated in the study, Scheper-Hughes (2001) highlights that findings deemed uncontroversial to the researcher can cause significant distress to those to whom the data relate. Thus, to promote anonymity I decided that, in presenting my results, I would not mention the professions of staff (some held unique position in the teams). Furthermore I have not used any quotes that I felt would allow individuals to be identified, rather I have described the essence of the information contained within such quotes.¹⁹

4.8.2 Use of online discussion forum data

During my search for documentary evidence I came across parenting websites in which members used online discussion forums to talk about potential participation in EAT. In these forums parents expressed their opinions about whether they would enrol their children in the trial and discussed their views of research more generally. I felt that these forum conversations provided useful insights for the study.

Several authors highlight how Internet technologies such as online discussion forums offer ready access to research data, particularly from hard to reach groups (Brownlow and O'Dell 2002; O'Brien and Clark 2010). Whilst these technologies offer easy access to data, Moreno et al. (2008) point out that this method is unlikely to provide representative data as it excludes those who cannot access the Internet or who would not choose to contribute to a discussion forum.

¹⁹ In Chapter 8 I have described the stories of the three parents who withdrew their children from the trials in a level of detail that might compromise their anonymity. I discussed this with one of the mothers who agreed it was acceptable for her to be identifiable. Following interviews with the staff it was evident that the stories of the other two parents bore similarities to the circumstances in which other parents (who had not consented to be interviewed for the study) had withdrawn their children. Thus I felt that it was possible to maintain anonymity even though a greater level of detail would be presented.

Although the information provided in such forums are considered to hold value for research, questions exist regarding the acceptability of its use, particularly without the express consent of those who have contributed to the forum (Hoser and Nitschke 2010; Heilferty 2011). As yet, no clear guidelines exist, but Eysenbach and Till's (2001) paper is often referenced with regards to this issue. They propose that a useful way of establishing whether it is acceptable to use data without obtaining consent is to consider whether the online discussion forums are public or private, an accepted standard when it comes to observation methods that are used in ethnographic studies. They argue that discussion forums that can be viewed without membership, subscription, registration or the need for a password, and sites with large numbers of page views or memberships may be considered to be public.

I felt that the discussion forums that I came across fell within the public category. I had not actively sought out this form of documentary data; rather I had come across them in the course of a general Internet search. No subscription or membership had been necessary; I was able to view the discussion simply by clicking the link from the Internet search engine page. Furthermore, the websites had a large number of page views. Whilst I deemed that it would be acceptable to use this data without the consent of those involved, I decided to take additional steps to promote confidentiality. In the results chapters I have presented the essence of the arguments that were put forward and attributed these views to the contributors to the online discussion forums, but have not directly quoted from or referenced the websites. It should be noted that whilst this decision helps to uphold the ethical principles of informed consent for participation and confidentiality, it does limit the transparency of the research process.

Having described the methods used to collect and analyse the data and discussed some of the ethical issues that arose during this process, in the following section, in line with the ethnographic approach that was taken to data collection, I present a reflexive account of the way my previous knowledge and experience has influenced this thesis.

4.9 Reflexivity: influence of the researcher on data collection

As my previous knowledge and experience is fundamental to the way in which data were collected and interpreted (Gerstl-Pepin and Patrizio 2009) in this section I describe my previous role, as a nurse who helped to set up LEAP, before discussing how the role I adopted during the observations influenced the data that I collected.

In July 2003 I began a new position as a research nurse in the paediatric allergy department of a London hospital where I was in charge of the day-to-day running of two industry funded paediatric drug studies. In 2004 the lead clinician in the department began to plan LEAP, and from an early stage I assisted with the initial concept proposal and funding application. I became more involved once funding was obtained, giving input at the weekly protocol development meetings, planning the initiation of the trial, interviewing nurses, dietitians and administrative staff to carry out a feasibility exercise, and providing training and support to these staff members. During protocol development the team moved to a different hospital and I was involved in the planning of this move, including helping to design and equip the clinical trials unit in which LEAP and EAT would eventually be conducted.

I was involved in the feasibility stage of LEAP, looking at whether it would be possible to recruit adequate numbers of children. Once LEAP began I worked on the trial, conducting the visits that children attended with their parents and assisting with recruitment and amendments to the protocol. I also managed the nursing staff that worked on LEAP and

provided support to other staff where necessary. I continued in this role until January 2008 when I took leave to travel for six months before undertaking a full time MSc and subsequently this PhD. However, I maintained contact with the trial staff throughout my MSc, assisting with interviewing new staff when the new senior nurse was on maternity leave. My MSc and PhD were funded through fellowships, the terms of which meant that I would return to LEAP once I had completed my studies. Consequently, although I was not actively involved in the daily activities of LEAP, my profile remained on the LEAP website and staff were aware that I would return once I had completed my PhD.

I have provided this description of my previous role as I consider it is likely to have influenced this research. My previous experience of LEAP has influenced the way in which I collected and analysed data, the familiarity of the setting affecting the way in which I viewed the data (Hammersley and Atkinson 1995). Some argue that such familiarity reduces the objectivity of the findings (Miller 1952; Wind 2008). However, as it is impossible to escape these experiences, others suggest that they should be made explicit (Pillow 2003).

During my fieldwork I kept a reflexive diary in which I tried to consider how my previous experiences related to the data I was gathering. I had previously held a senior position in LEAP, interviewing and managing many of the staff and recruiting parents. Hammersley and Atkinson (1995) extol the virtues of 'impression management' in building relationships in the field. Whilst they refer mainly to physical and sartorial characteristics, I would suggest that this extends to the impression that staff and parents, particularly those who knew me in my previous role, had of me before I began my fieldwork. As I go on to describe, these impressions are likely to have had an influence on the way staff and parents related to me, particularly at the beginning of my observation period.

Having previously been embedded in the daily activities of LEAP, when I began my relatively non-participatory observer role I initially felt very conspicuous. Whether for this reason or purely because I was there staff often commented on my presence, as this excerpt of field notes from the second day of my observation period illustrates:

There was quite a lot of banter because there was going to be a presentation to Oliver²⁰ for his birthday over in the offices and a few people were going to go over. One staff member starting singing 'Happy Birthday' to demonstrate how she would sing and dance for the presentation and everyone was laughing. Then she suddenly looked at me, took my hand and said 'Oh no, the big boss [referring to me in my old role]²¹ is here watching me and I've been dancing and singing – don't write that down' (I didn't have a pen or paper in my hand). I laughed and said that I wasn't the big boss anymore and that it didn't matter to me if people sung and danced, that it was nice to see her happy. She seemed reassured by this and carried on laughing. [Field notes 27th May 2010]

This passage is just one example of a similar conversation I had on many occasions at the beginning of my fieldwork. Although I had explained the purpose of the study and frequently re-iterated this explanation, some staff expressed concern that I was checking up on their behaviour and/or reporting back to the LEAP and EAT PI. Although behaviour modification in observational studies is well described (Vidich 1955; Spradley 1980; Atkinson and Hammersley 1994), interestingly, staff tended to acknowledge my observer status only *after* behaviour that they considered I might deem 'inappropriate' such as shouting across the room to get another staff member's attention, singing and laughing loudly, or cheering. After about three months of observation the staff mostly stopped questioning whether I was going to 'report' incidents such as the one above and often

²⁰ To protect confidentiality pseudonyms are used throughout the thesis in place of the real names of the staff and parents. I invited staff and parents to chose their own pseudonym but most preferred to let me pick a name for them.

²¹ Text in square brackets within data extracts has been added to provide clarification for the reader

came to chat to me when they had a spare five minutes. These informal interactions provided additional useful data that I could not have gleaned from observation alone, including information that had not been mentioned in the semi-structured interviews I conducted with staff.

4.10 Conclusion

An ethnographic approach, in which two RCTs were used as case studies, was used to collect data for this thesis. In this chapter I have attempted to provide a transparent account of the data collection and analysis. I have also highlighted some of the difficulties I faced during the data collection period, including procedural difficulties and problems with upholding the ethical principles to which researchers must abide.

In the following chapter I provide further details about the two RCTs. I also present a description of the local and wider context in which the trials were conducted and outline the characteristics of the staff and parents who agreed to take part in the study.

Chapter 5: The field of the study

In the previous chapters I provided a rationale for the study, outlined the aims and objectives and described the methods that were used to collect data. In this chapter, prior to presenting the findings of the study, I describe the two RCTs that were used as case studies for the fieldwork, provide information about the parents who participated in the interviews and the staff who participated in the interviews and observations, and depict the setting in which the fieldwork was conducted. However, first I describe the wider background against which the trials were taking place, beginning with the topic that the trials were addressing: childhood food allergy.

5.1 Childhood food allergy

Food allergy is a term that often has different meanings within the public and medical communities (Nettleton et al. 2009). Whilst the public tend to use it to describe any symptoms that occur following the consumption of a food, the medical community categorises food allergy according to the pathophysiological processes that underpin the symptoms that an individual experiences.

Food allergy may be 'Immunoglobulin E (IgE) mediated' or 'non-IgE mediated'. The mechanisms that underpin non-IgE mediated food allergy are, as yet, unknown, but it manifests with a wide variety of symptoms, including skin rashes, abdominal pain and bloating. Non-IgE mediated food allergy is more commonly referred as an 'intolerance'. The pathophysiology of IgE mediated food allergy has been defined. IgE mediated food allergy occurs due to a dysregulation of the immune system which leads to an imbalance in the production of T cells and thus to *pathogenic* production of IgE antibodies (Sellegge and Bischoff 2008). IgE mediated food allergy manifests with symptoms that include

urticaria (hives), angioedema (swelling of the soft tissues such as eye lids or lips), vomiting, diarrhoea, wheezing and, in extreme cases, anaphylaxis (Bjorksten 2008). It is IgE mediated food allergy (for simplicity, henceforth referred to as 'food allergy') that LEAP and EAT were investigating.

Food allergy belongs to a group of other IgE mediated conditions including eczema, asthma and hay fever, which together are known as atopic disorders (Wright 2004).

Children with one of these conditions are more likely to develop additional atopic disorders, and the notion of the allergic march, in which infants begin with eczema and subsequently develop food allergy, asthma and hay fever has gained considerable kudos in the recent past (Wahn 2000; Gore and Custovic 2004).

Although the mechanisms underpinning food allergy have been defined, quite why the immune system undergoes a dysregulation is, as yet, unknown. A variety of theories have been postulated and the hygiene hypothesis is perhaps the most frequently cited. The hygiene hypothesis was first suggested by David Strachan (1989) to explain why children experience allergic rhinoconjunctivitis (more commonly referred to as hay fever). He developed the theory in response to his epidemiological study findings that children with older siblings had a lower incidence of hay fever than first borns. He argued that modern living conditions had resulted in reduced exposure to the infectious agents that were necessary to prevent the immune system from undergoing the 'over-reaction' to everyday substances experienced by individuals with IgE mediated allergies, but that children with older siblings were perhaps more likely to be exposed to infection. Although the theory was initially proposed as an explanation for hay fever, it has also been discussed in relation to other atopic diseases, including food allergy. However, to date, the theory is unproven.

An emerging theory with regards to food allergy is that of oral tolerance induction. This theory proposes that tolerance (the absence of allergy) is only achieved by the orogastric route, i.e. by eating a food (Paschoal et al. 2009). The theory has been proven in murine models, where mice that were fed substantial quantities of a food developed tolerance when subsequently immunised with the relevant food protein, whereas those that had never eaten the food demonstrated allergic symptoms after such immunisation (Strid et al. 2004; Paschoal et al. 2009). LEAP and EAT were designed to investigate whether oral tolerance induction can help to explain why humans develop food allergies.

Diagnosis of food allergy is difficult; the non-specific nature of the symptoms may be attributable to alternative conditions or occur idiopathically, and may consequently be overlooked by clinicians with limited experience of allergic disease (Clark 2008).

Population based studies estimate the prevalence of childhood food allergy to be between 1.6% and 6% (Pereira et al. 2005; Venter et al. 2006a; Venter et al. 2008), although the lay public tend to overestimate the incidence of the condition. A birth cohort study conducted on the Isle of Wight found that, whilst parental report suggested an incidence of food allergy of between 5.5% and 14.2% in children between the ages of 3 and 12 months, objective assessment found it to be between 2.5% and 5.5% (Venter et al. 2006b). This difference may reflect differences in the medical community's and public's understanding and use of the phrase 'food allergy'.

Food allergy presents a considerable burden to children, families and society. Owing to the potential for an allergic reaction to cause life threatening symptoms, the lack of available treatment and the fact that children must practice strict avoidance of the offending foods (Eigenmann et al. 2008), the psychological burden of food allergy on families is considerable. Families with food allergic children have a significantly reduced

quality of life (Sicherer et al. 2001) and are more anxious about their condition than those with a child with insulin dependent diabetes mellitus (Avery et al. 2003). Although no studies have quantified the financial costs of food allergy in the UK, this burden is likely to be substantial (House of Lords Science and Technology Committee 2007) with direct and indirect costs being incurred by the health service, food industry, employers, consumers, carers and regulatory bodies (Miles et al. 2005). Furthermore, whilst some children outgrow food allergy, many continue to be allergic into adulthood (Roberts and Lack 2003); hence the psychological and financial burdens of food allergy persist.

There has been limited sociological investigation into food allergy. Nettleton et al. (2009) suggest that there are similarities between discussions about food allergy and other contemporary phenomena such as climate change and global terrorism, particularly with regard to notions of uncertainty and risk. They highlight the growing media attention that food allergy has received and argue, as do Rous and Hunt (2004), that societal concern about food allergy is disproportionate to the prevalence of the condition. Rous and Hunt (2004) suggest that this heightened concern has a moralizing character which reflects a wider concern regarding the protection of children, a view that is shared by Wolf (2011) and that I will discuss in greater detail in the following sections and later results chapters.

In the following section, before describing the trials that were used as case studies for this research, I depict the wider context in which they were conducted.

5.2 The context in which the trials were conducted

In exploring the context in which the trials were conducted I adopt Bourdieu's (1992) assertion that practice is influenced by a variety of interacting 'fields'. During data analysis there was evidence that the practices of four additional fields were relevant to

the trials: medical research; allergy healthcare; infant feeding; and parenting. These fields are introduced in the following sections.

5.2.1 Medical research

In Chapter 1 I described the field of medical research in some detail, discussing the paradigm shift towards evidence based medicine and the centrality of the RCT to this movement. The field of medical research has been strongly influenced by the field of scientific research and particularly by the philosophy of that field, which prizes the creation of abstract, universal and formalised knowledge that is highly reliable and valid (Epstein 1996; Latour 1998; Lidskog 2008; Moreira 2011). Epstein (1996) argues that the alignment of the two fields legitimises medical research and, furthermore, the field of medicine, by placing objectivity at their core.

In Chapter 1 I also discussed how the history of the field of medical research was characterised by incidents in which participants had been harmed or exploited, and described how this had led to the development and implementation of ethical guidelines and legislation to promote the protection of those who take part. Despite these guidelines some members of the public are mistrustful and sceptical of both medical and scientific research (Epstein 1996; HM Treasury 2004; Wynne 2006). This mistrust is not only attributable to the harm that previous generations of research participants have suffered, but also to the fact that governments have used science as way of attempting to exert authority over the public (Wynne 2006).

Whilst science and, more particularly, knowledge of science used to be the sole domain of academics, Lidskog (2008) argues that two generations of mass higher education has brought about an increase in scientific knowledge amongst the public. This has resulted in the 'entanglement' of science and society (Latour 1998) and changes in the field. Perhaps

for this reason and reflecting the move towards a less paternalistic health service, rather than simply being the subjects of research, patients and the public now help to shape the direction of medical research, although the extent of their influence is variable (Epstein 1996; Latour 1998; Fudge et al. 2007).

5.2.2 Allergy healthcare

Around the time²² that the trials were taking place, the House of Lords Science and Technology Committee (2007) conducted an investigation into allergy within the UK. They brought together a range of evidence highlighting that, whilst the UK was conducting high quality research into allergic diseases, the provision of health services for those with allergies was poor. They heard evidence that a lack of training, expertise and incentives to provide allergy services within primary care was leading to patients experiencing delays in diagnosis and referral to appropriate specialist services. Inadequacies in training had also caused a dearth of specialist clinicians in allergic disease, meaning that patients who were referred to secondary or tertiary care were often treated by HCPs who lacked the requisite expertise. This resulted in patients receiving symptomatic rather than preventative treatment and thus their 'complex' needs were often unmet. Furthermore, allergy specialists told the Committee that the commissioners of healthcare services did not view allergy as an important subject and so allergy training and healthcare provision were unlikely to improve. The Committee concluded their report by recommending that allergy centres that brought together a multidisciplinary team of experts be opened in

²² The notion of time is frequently debated in ethnographic research. This debate revolves around whether ethnographic accounts should be presented in the past or present tense: to use the past assumes that those who took part in the study are 'frozen in time'; whilst to use the present assumes that they do not progress or change (Willis 2010). In this account I use the present tense when describing fields that are very broad and that consequently take many years to change and the past tense when describing smaller fields, including the trials, that change more rapidly. However, I acknowledge that, when using the present tense, the various fields will have continued to evolve after my data collection was complete.

every Strategic Health Authority, and that medical training be improved so that the needs of patients with allergic conditions who accessed healthcare in the UK could be met.

5.2.3 *Infant feeding*

Practices within the field of infant feeding are heavily influenced by the policies of the UK Department of Health (DoH). These policies are based upon a notion of dietary exclusion. Parents are advised that infants benefit from being exclusively breastfed (no formula milk or solid food) until six months of age and until midway through the recruitment period of one of the case study trials (LEAP), were advised not to give their children peanut containing foods until they were three years of age.²³

Although these policies are strongly promoted by the DoH, they are not underpinned by sound scientific evidence. The House of Lords Science and Technology Committee (2007) review into allergy concluded that there was limited evidence to suggest that the avoidance of peanut would help to prevent peanut allergy, and, following their recommendations, the DoH withdrew this advice in 2008. Wolf (2011) provides a comprehensive discussion of the limitations in the evidence supporting the practice of exclusive breastfeeding. Although many studies have found that breastfeeding affords children superior health and intelligence, their observational designs mean that these benefits might be the result of confounding factors. Kramer and Kakuma (2002) conducted a systematic review of studies exploring the health effects of breastfeeding duration. Whilst they concluded that there were '*no apparent risks*' (p.2) to recommending exclusive breastfeeding for the first six months of life, with one

²³ This guidance represented a belief that peanut avoidance would prevent peanut allergy, rather than that peanuts may be a choking hazard for young children.

exception²⁴ they found no benefits over mixed or formula feeding. They also commented on the lack of gold standard evidence and called for RCTs to be conducted in this regard.

That scientists have been unable to uncover the mechanisms by which breastfeeding is beneficial to children's physical health and intelligence provides an additional question mark as to the superiority of breastfeeding. Yet, despite the lack of evidence, the DoH, international governments and high profile organisations such as the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) strongly promote breastfeeding as a beneficial practice. This discordance led Wolf (2011) to propose that:

...the superiority of breastfeeding is one of the rare 'facts' about reproduction and childcare that inspires widespread agreement among and between the medical community and the public, consensus that exists despite critical flaws in the scientific evidence that has inspired dubious public health claims. [p.106]

Bourdieu (1990) suggests examining the history of a field when exploring practice and Dowling (2005) described how, from antiquity until the 1800s wet nurses were frequently employed to breastfeed infants. In the late 1800s women were expected to take more responsibility for their children and seeking expert opinion as to the best way to feed and care for a child was commonplace amongst the middle and upper classes. At this time the medical profession frequently advocated formula feeding for mothers of young children, as both respite for tired mothers and as a way of monitoring and controlling infants' diets (Dowling 2005; Wolf 2011). However, in the 1960s this paternalistic stance was challenged by women's health advocates, whose exhortations of the rights of mothers to choose how to feed their infants without interference grew in popularity. Coupled with breastfeeding's centrality to a campaign that highlighted the unethical practices of

²⁴ They did find that breastfeeding offers protection against gastrointestinal infections.

formula companies who marketed their products to mothers living in the developing world, by the 1980s breastfeeding was championed by mothers, healthcare societies and international organisations (Wolf 2011). Such endorsement means that, in Western societies, breastfeeding discourses have become couched in notions of morality, both in terms of breastfeeding in public and with respect to mothers' choices regarding whether to breastfeed their children (Van Esterik 2002). The moral nature of discourses regarding how mothers choose to feed their infants is also likely to reflect the values of the field of parenting that are discussed in the following section.

5.2.4 Parenting

The use and meaning of the terms 'parent' and 'parenting' have evolved substantially from the 1960s, when they were used infrequently, to the early 2000s when their use became more commonplace (Lee et al. 2010; Gillies 2012). Whilst parenting a child used to be a private matter within a family, Gilles (2012) argues that, in the 1990s, the UK Labour government repositioned the field such that parenting became a public concern. Rather than representing a familial bond underpinned by love and care, parenting has now come to be viewed as a way of tackling social problems: 'good parenting' results in 'good children' who grow up to become 'good citizens'. Strong (1979) also discussed the public nature of parenting, within the medical sphere at least, in his ethnography of paediatric clinic consultations. He suggested that physicians frequently judged parents' abilities, and parents who deferred to the experience of the physician were judged to be 'good parents'.

Several authors argue that official discourses about the field of parenting have taken on a moral dimension in which parents are required to put the needs of their children first (Strong 1979; May 2008; Francis 2012; Gillies 2012). This value has become deeply

embedded and, in Bourdieu's (1977) terms, now represents the collective habitus of the field.

Beck (1992) argued that society has become focused on risk, and several authors consider that the field of parenting is strongly influenced by this notion (see for example Lee et al. 2010; Wolf 2011). In the 21st century, children are considered to be at constant risk of harm and thus in need of protection both by their parents and from their parents (Gillies 2012). For this reason, and owing to parenting's aforementioned centrality to citizenship, the field has become a central focus of UK politics, and is subject to considerable intervention by individuals and organisations with no relational bond with children (Gillies 2012; Lee et al. 2010). Policy makers now 'enable' parents to raise their children (Lee et al. 2010) against standards that reflect the values of the middle classes (May 2008).

Having discussed the wider context against which the trials were conducted, in the following section I describe the 'fields' of trials: the two RCTs that were used as case studies for this research.

5.3 LEAP and EAT: the case study RCTs

The aim of this research was to further understanding of participation in non-therapeutic paediatric RCTs and consequently I needed access to such trials. Before starting my PhD I worked as a research nurse in the paediatric allergy department at Guys and St Thomas' NHS Foundation Trust (GSTFT). This department was conducting two investigator led, single centre RCTs, LEAP and EAT, that were exploring whether it was possible to prevent young children developing food allergy.

The three objectives of this study span the duration of a child's participation in an RCT, considering recruitment, adherence and retention. At the time I collected the data LEAP

and EAT were at different stages and I considered each would contribute to different objectives. As EAT was actively recruiting children I felt that it would be possible to gather information about recruitment close to the time when parents made their choices, thereby minimising recall bias (Bowling 2002). LEAP, however, had finished recruitment two years previously and staff were beginning to plan for the participants' final visits. As the families had been participating in LEAP for between two and four years I thought that data gathered from LEAP would be the most relevant to the objectives exploring adherence and retention in the trials. Despite these initial assumptions, once I began collecting data I realised that both trials provided interesting data for each stage of research participation. Consequently data from LEAP and EAT were used to address all objectives.

In the following sections I describe each trial in some detail, beginning with LEAP.

5.3.1 The Learning Early About Peanuts trial (LEAP)

LEAP aimed to prevent peanut allergy in young children who, by virtue of having severe eczema and/or egg allergy, were at high risk of developing the condition (Sicherer et al. 2010). Infants were randomised to consume or avoid peanut and LEAP's primary outcome was the difference in rates of peanut allergy between the groups when the enrolled children were five years of age. It was hypothesised that early consumption of peanut would protect against the development of peanut allergy.

LEAP recruited children using a variety of methods. Flyers were sent to home addresses of children living in and around London using a commercial database that holds the names and addresses of 97% of UK children aged less than 12 months. HCPs who were likely to see appropriate children (e.g. general practitioners, paediatricians, dermatologists, allergists, health visitors and dietitians) were sent information about LEAP or visited by

LEAP staff to discuss collaboration with recruitment. During the recruitment period some LEAP staff gave television and radio interviews about allergic disease during which they discussed LEAP and broadcast contact details for interested families.

LEAP enrolled 640 infants aged between four and eleven months who met the inclusion criteria of severe eczema and/or egg allergy. Recruitment took place between December 2006 and May 2008. Children randomised to the intervention ate a peanut-containing snack three times a week, at home, until the child was five years old. Those randomised to the control arm avoided all forms of peanut (except trace amounts) for the same duration.

Children attended five scheduled visits over the duration of the trial and parents completed three-day food diaries regarding their child's diet prior to each visit. All visits took place on a clinical trials unit that was dedicated to LEAP and EAT. Parents were reimbursed for the costs of travel to attend the visits. Children also received small gifts (e.g. a cup and colouring book) at the 12, 30 and 60 month visits. Table 4 (p.140) details the five scheduled and one unscheduled LEAP visits.

At the randomisation and 60 month visits, children underwent an 'oral food challenge' (OFC)²⁵ in which they consumed a set quantity of peanut and were monitored for signs of allergic reaction. Between the scheduled visits LEAP staff phoned parents in both groups on a regular basis to gather safety data and information about peanut consumption and avoidance. In addition to the planned visits, any child who was randomised to peanut consumption but for whom there was a concern they had become allergic to peanut was

²⁵ Oral food challenges are used to diagnose allergy. They are performed under medical and nursing supervision and commonly take one of two forms: a cumulative challenge in which children are given a set amount of food in one large portion, and an incremental challenge in which incremental doses of a food are given at set intervals. The incremental challenge is usually used where there is significant concern that the child is allergic; the grading of doses reduces the risk of a serious allergic reaction, but increases the time commitment. Children are monitored throughout for signs of allergic reaction. The challenge is discontinued and appropriate treatment administered if an allergic reaction occurs.

invited to attend an unscheduled visit to ascertain whether it was safe for them to continue consuming peanut.

Visit	Screening	Randomisation	12 month	30 month	60 month	Unscheduled
Visit occurs when child is aged:	4-11 months	1-21 days after screening visit	One year	Two and a half years	Five years	Any age
Procedures:	Physical examination Questions regarding child and family health and diet Skin prick testing Blood testing	Physical examination Questions regarding child and family health and diet Oral food challenge (if randomised to peanut consumption)	Physical examination Questions regarding child and family health and diet Skin prick testing Blood testing	Physical examination Questions regarding child and family health and diet Skin prick testing Blood testing	Physical examination Questions regarding child and family health and diet Skin prick testing Blood testing Oral food challenge (all children)	Physical examination Questions regarding child and family health and diet Skin prick testing Blood testing Oral food challenge
Visit duration (approx)	1 hour	1-2 hours*	1 hour	1 hour	2 hours*	2 hours*
Telephone calls	N/A	Weekly until V12	Fortnightly until V30	Monthly until V60	N/A	N/A

* Children who showed sensitivity to peanut on skin prick testing and who were randomised to the peanut consumption group were given an incremental rather than a cumulative peanut challenge. These visits lasted 4-8 hours.

Table 4: LEAP visit details

5.3.2 The Enquiring About Tolerance trial (EAT)

EAT aimed to prevent the development of the six most common childhood food allergies, milk, egg, wheat, fish, peanut and sesame, in the general population of children. Infants were randomised to early consumption of these foods or to exclusive breastfeeding until six months of age. EAT's primary outcome was difference in the rates of allergy to the six

foods when the children were three years old. It was hypothesised that early introduction of these foods protects against the development of allergies.

Recruitment to EAT began with an initial period in which the trial investigators aimed to enrol mothers when they were pregnant. In this phase recruiters attended the antenatal screening clinics of two London teaching hospitals and invited mothers to consider participation in the trial. As will be discussed in Chapter 6, due to poor rates of accrual this method of recruitment was later abandoned and subsequently most children were recruited using flyers that were sent to the homes of parents throughout the UK using addresses from a commercial database that holds the names and addresses of 97% of UK children aged less than 12 months. As for LEAP, some parents were referred by HCPs who were aware of the trial through connections with the trial investigators or previous collaboration with LEAP.

Between March 2009 and May 2012 1302 children who were between three and four months of age were enrolled in EAT. Parents of children randomised to the intervention were asked to follow a weaning schedule designed to ensure that the children had consumed all six foods before the age of six months; those whose children were randomised to the control arm were asked to exclusively breastfeed their child until six months of age, after which parents introduced foods as they wished.

Children attended three scheduled visits to the clinical trials unit over the duration of their trial participation. Parents were reimbursed for the costs of travel to attend the visits. Table 5 details the timing of the visits and the procedures that took place.

Visit	Screening	V12	V36	Unscheduled
Visit occurs when child is aged:	Between 3 and 4 months	One year	Three years	Any age
Procedures:	Physical examination	Physical examination	Physical examination	Physical examination
	Skin prick testing	Skin prick testing	Skin prick testing	Skin prick testing
	Questions regarding child and family health and diet	Questions regarding child and family health and diet	Questions regarding child and family health and diet	Questions regarding child and family health and diet
	Blood testing	Blood testing	Blood testing	Blood testing
			Oral food challenge	Oral food challenge
Visit duration (approx)	1 hour	1 hour	2 hours*	4-8 hours*
Online questionnaire	Monthly until V12	Three monthly until V36	N/A	N/A

*Children who had a positive skin test or had shown signs of an allergic reaction to any of the six trial foods at home attended for an incremental oral food challenge. Their visits lasted 4-8 hours.

Table 5: EAT visit details

In addition to the three planned visits, children in the intervention arm of the trial who had a positive skin prick test to any of the six trial foods, and any child who experienced an allergic reaction to any of the six foods at home attended an unscheduled visit for an OFC. All parents were asked to complete online questionnaires²⁶ regarding their child's consumption of the six foods at regular intervals throughout the trial. Prior to each trial visit parents were asked to complete a more detailed questionnaire about their child and family's health and diet.

Having provided an overview of the trials, in the following sections I describe the staff and parents who participated in the study.

²⁶ Parents who could not access the Internet or who preferred not to complete online questionnaires were able to complete paper questionnaires that were posted to them at the appropriate intervals during trial participation.

5.4 Characteristics of the staff and parents who took part in the study

5.4.1 *Staff*

Twenty six staff members contributed data to this thesis through interviews and/or observation. Staff members included the principal and co-investigators, research fellows, research nurses, research dietitians, trial co-ordinators, administrative staff and a phlebotomist. Staff who worked for the organisations funding LEAP and EAT or who sat on the steering committee of EAT were also interviewed. Table 6 illustrates the number of staff in each category. I did not collect demographic information from the staff who participated in the study.

Profession	LEAP	EAT	Total
Investigator (all paediatricians with specialist paediatric allergy expertise)	2	3	4*
Research fellow (all paediatricians)	1	1	2
Research nurse	4	2	6
Research dietitian	2	2	4
Phlebotomist	1	1	1*
Trial coordinator	1	1	2
Administrative staff (including trial recruiter)	1	1	2
Funder/steering committee member	2	3	5
Total	14	14	26*

*LEAP and EAT shared a PI and phlebotomist

Table 6: Professions of staff who took part in the study

5.4.2 *Parents*

Fifty six parents took part in fifty one interviews (in five interviews both the mother and father were interviewed together). Parents who chose not to participate in EAT, who were participating in LEAP or EAT, and who participated in LEAP or EAT but subsequently

withdrew were interviewed. The numbers of parents interviewed in each category is shown in Table 7.

	Child participating in		Total (number of fathers)
	LEAP (number of fathers)	EAT (number of fathers)	
Chose not to participate	n/a	7 (1)	7 (1)
Participating	31 (6)	16 (3)	46*(9)
Withdrew	1	2	3
Total	32 (6)	25 (4)	56* (10)

*1 mother had two children, 1 participated in LEAP and 1 in EAT

Table 7: Parent interviews by category.

In Appendix 16 I describe the parents who took part in the study individually, but a summary of their sociodemographic characteristics is provided here. Tables 8, 9 and 10 show the age group, ethnicity and educational level of parents who were interviewed. Most parents described their ethnicity as White British, were in the age category 31-40 and had been educated to at least degree level.²⁷ In a third of the families that were interviewed, at least one parent had a medical or scientific background.

Age group	Number of parents		Total
	LEAP	EAT	
21-30	2	6	8
31-40	24	17	41
41-50	6	1	7

Table 8: Age of parents who participated in the interviews

²⁷ I was not able to access data regarding the sociodemographic details of LEAP and EAT parents who did not take part in this study and thus am unable to assess whether these parents are representative of LEAP and EAT parents per se.

Ethnicity	Number of parents		Total
	LEAP	EAT	
White British	18	23	41
White Other	9	1	10
Black British	1	0	1
Black African	3	0	3
Chinese	1	0	1

Table 9: Ethnicity of parents who participated in the interviews

Level of education	Number of parents		Total
	LEAP	EAT	
Basic secondary	0	2	2
Advanced secondary	3	2	5
Diploma	4	1	5
First degree	16	13	29
Further degree	9	6	15

Table 10: Educational level of parents who participated in the interviews

Parental postcodes were used to calculate Index of Multiple Deprivation (IMD) scores, which use measures of income, health, housing, education and living environment to rank deprivation within specific geographical areas. Lower scores represent areas with the lowest deprivation. The mean IMD for the whole sample of parents was 22.02. The mean IMD for LEAP parents was 24.67 and for EAT parents was 18.17. The mean IMD for those who withdrew their children from the trials was 13.34 and for those who declined participation was 14.63.

I interviewed approximately equal numbers of LEAP parents from each randomisation arm (14 intervention v 15 control) but more intervention arm parents were interviewed

for EAT (11 intervention v 5 control). Each child whose parent withdrew from LEAP and EAT was in the intervention arm of the respective trial.

At the time that I interviewed parents their children had been participating in LEAP for an average of 31 months (range 16-42 months). An average of 2.8 months (range 1-6 months) had elapsed since parents made their decision about whether or not to enrol their children in EAT.²⁸

Having described the trials and the parents and staff who participated in the study I will now provide an overview of the setting in which I conducted my fieldwork.

5.5 The fieldwork setting

I conducted my observations of the RCTs in the setting in which they were taking place, a paediatric clinical trials unit (named 'Snowy Owl') that, at that time, was dedicated to LEAP and EAT alone. The unit was on the first floor of the Evelina Children's Hospital (known locally as 'The Evelina') which is on the St Thomas' site of Guys and St Thomas' NHS Foundation Trust.

St Thomas' sits on the south bank of the Thames, opposite the Houses of Parliament and beside the London Eye, affording an impressive view to visitors. The Evelina was a relatively new building that was purpose built to bring together all paediatric services at Guys and St Thomas'. Completed in 2005 it prides itself on being a '*hospital that does not feel like a hospital*'.²⁹ Children and their families were consulted about the design, and the result is a building that uses 6.500 square metres of glass to achieve a light, bright environment.

²⁸ N.B. This figure does not include the two parents who withdrew their children from EAT, who both made the decision to enroll over 2 years previously and who had withdrawn a few months after enrolling.

²⁹ Evelina Children's Hospital Website (accessed 27th January 2012)
<http://www.guysandstthomas.nhs.uk/services/childrens/evelina/history/design.aspx>

A reception desk was situated at the entrance of the Evelina, to the right was a small cafe and to the left the children's pharmacy. The rest of the ground floor was devoted to outpatient clinics. Clinic rooms were arranged around the edge of the building and the waiting area was situated in the central space. During working hours this area was often very busy, occupied by parents and children waiting for appointments. Closest to the entrance was a cafe style eating area with tables, chairs and high chairs for small children. Beyond was padded bench-style seating. This seating was interspersed with activities such as X box Kinect stations, a television with video camera above that placed children on the screen with a backdrop of an 'exotic location' such as the pyramids in Cairo, as well as boxes of more traditional toys. At the far end was a brightly coloured helter-skelter, the top of which reached the level of the first floor. At either end of the waiting area was a glass lift.

Families attending LEAP and EAT walked through the outpatients department and took one of the lifts to the first floor where departments were arranged around a central atrium. Each floor had a theme, the first floor being 'The Arctic'. All departments on this floor were named after Arctic animals and the general colour scheme was shades of blue and grey. Rather than using traditional signage, each department was denoted by a large coloured Perspex animal that was attached to the wall beside the entrance. The walls of the department that faced the central atrium were made of glass and the departmental animal was also depicted in frosted stickers positioned at about adult chest height at metre intervals along the glass. Although novel, this more subtle way of naming departments meant that parents were often to be seen wandering around the atrium. Inside the clinical trials unit, the staff who awaited the arrival of a participating family often went to the door to ask 'lost' looking parents with children of an appropriate age

whether they were attending LEAP or EAT. Parents who found their way to the unit without such assistance pressed a doorbell and were greeted by the sound of an electric door release, often followed by a member of staff who made their way towards the door to assist the parent, with at least one child and usually a pushchair, to negotiate the narrow entrance.

The unit was a friendly place where the staff and parents interacted in an informal way. The staff introduced themselves by their first names and usually their profession; most wore everyday clothes although some of the nurses wore a uniform. The unit was set out in a similar way to a hospital ward, with a large nurses' station overlooking a two-bedded and a four-bedded bay. Each bed space had an electric bed with plastic cots sides and the mattresses were covered by a single white sheet. On one side of each bed was a comfortable chair, on the other a bedside locker with a small television on top. On the wall behind each bed were devices for administering oxygen and suction. The walls, curtains, floors and chair coverings were varying shades of blue, and brightly coloured boxes of children's toys were placed against the back wall of the unit, underneath windows that looked out onto the hospital gym and beyond, the grounds of Lambeth Palace.

The unit had one large bathroom and a second smaller toilet. Beside the two-bedded bay was a separate treatment room that was used for taking blood. This room had a desk at the back of the right hand wall, and a treatment couch on the back wall. On the left wall were fairy lights and two large fridges, one of which had a television on top, which had cartoons playing on it. On the top wall, to the left of the door, was a low trolley containing the necessary equipment for taking blood. On the top of this trolley were several brightly coloured children's toys: a 'piano' with cartoon characters above each

key, a disco ball and various smaller items such as cars or plastic animals that had been taken into the room by children before their blood test. Two chairs were placed at right angles to the trolley for parents to sit with children when they had their blood taken.

Once the staff member who welcomed the family had established which trial they were attending the family were directed to a bed that they used as their base and invited to make themselves at home. One member of staff (usually a nurse or doctor) looked after each child, with other members of the team providing expertise when necessary. The person that welcomed the parents usually offered them a drink and if the member of staff who was due to conduct their visit was not readily available they were informed that 'X who is looking after you today will be with you soon'. If the staff member was in the vicinity they often greeted the parent and child and told them roughly how long before they would be free. Parents used this time to settle the child into the unit, taking off coats, getting them out of their pushchairs and finding some toys to keep them entertained, although older children tended to make a beeline for the toys as soon as they arrived.

The families attended the unit for one of three types of visit. At the start of both LEAP and EAT children attended a 'screening' visit, at which parents were given an opportunity to ask questions about the trial and, if happy to take part, to provide consent for their child's participation. At the time of the observation LEAP had finished their screening visits but EAT were still ongoing. Parents considering participation in EAT had had at least one episode of telephone contact with the trial staff prior to their first visit and had usually received written information, including the parent informed consent form that they completed if they decided to take part. The staff member conducting the appointment asked whether the parent(s) had received the written information and had time to read

through it. Parents who had not were given a copy and invited to take their time to read it. All parents were asked whether they had any questions about the trial. Few did, but any questions they did have were answered and the staff gave all parents a brief summary of the trial including an explanation about why it was taking place. They also reminded parents that there would be two groups in the trial, an early introduction (intervention) group and a standard weaning (control) group and asked if they understood that, as the trial was randomised, they could not choose to which group their child would be allocated. If parents confirmed that they understood this and were happy to accept allocation to either group then the staff member checked whether they were happy to go ahead and sign the consent form. Due to the telephone and email conversations that had taken place between parents and staff prior to this screening visit, few parents who attended the visit chose not to participate. The staff also ran through a checklist to confirm that the child was still eligible for participation prior to the consent form being signed. On rare occasions children were found to be ineligible and thus not enrolled onto the trial.

The staff member then outlined the procedure for the rest of the visit: that they would conduct the randomisation to see to which group the child would be assigned, conduct a physical examination, perform skin testing (if the child was randomised to the intervention), ask questions about the child's health and family history, and then the child would have a blood test at the end of the visit. They often gave the parent a rough time frame for the visit ('we'll do X, Y, Z and then hope to get you out of here in an hour'). After briefly leaving the parents to complete the online randomisation, a time during which parents often waited with anticipation for their 'preferred' group, the staff member returned to them to tell them the outcome and to conduct the rest of the visit.

Once the necessary trial procedures had been conducted they asked the dietitian and/or doctor (if necessary) to come and see the family. Depending on the availability of these staff members and of the phlebotomist, the child and accompanying parent(s) were also taken into the treatment room for the child's blood test to be taken. Once all the trial procedures had been completed either the dietitian or the staff member who had been conducting the consultation usually thanked the family for coming and helped them to the door, often reminding them that they were free to get in touch if they had any questions or concerns.

During my observation period children also attended the unit for interim scheduled visits at one year and, for LEAP, when the children were thirty months of age. These visits involved a physical examination, skin testing and blood testing and, with the exclusion of the consent and randomisation process, were very similar to the screening visit. Parents were given feedback about the results of the skin testing and often had quite lengthy discussions about their child's diet, food allergic status and general state of health, particularly with regards to their other allergic diseases, such as eczema, asthma and hay fever. These visits usually lasted one to one and a half hours.

Other families attended the unit for food challenges. These were carried out for: a) any child in the EAT intervention group who had a positive skin test;³⁰ b) any child in EAT who attended the one year visit and had a positive skin test but the parent reported the child was eating the food³¹ or any child who had had an allergic reaction at home; and c) any child in LEAP where there was suspicion of allergy to peanut or one of the other foods which formed the secondary outcomes of the trials. These visits were scheduled after

³⁰ To establish whether the child was allergic and minimise the risk of an allergic reaction at home.

³¹ As skin tests and clinical history were discrepant the food challenge was needed to definitively establish whether the child was allergic or not using gold standard criteria

discussion with the parents either at one of the other visits, or by telephone if the parent contacted the staff to report that their child had had an allergic reaction.

When undergoing a food challenge visit the families were asked to attend the unit as early as possible (usually arriving between nine and ten o'clock). The procedure was explained to the parents (and children where appropriate) who were asked to sign a consent form. The child was then given a brief physical examination, looking at their skin, listening to their chest and checking their vital signs. The nurse usually conducted the food challenges, although all children were seen by a doctor who was present on the unit for the duration of the challenge and who sometimes conducted the challenge themselves. The dietitians prepared the foods for the challenge and spent some time with the parents discussing the child's diet, particularly in relation to avoidance or introduction of the foods being challenged.

The food challenge involved giving the child increasing sized portions of the relevant food and monitoring them for signs of an allergic reaction. The number of doses varied from four to seven with twenty minutes elapsing between each dose. The child was also monitored for two hours after the final dose (or at least two hours after any allergic reaction) and so this visit took a minimum of four hours, but could take longer if the child struggled to eat the food. The monitoring involved checking vital signs about fifteen minutes after each dose, re-examining the child's skin and listening to their chest.

Children were not allowed to leave the unit for the duration of the challenge; most played with the toys or watched DVDs. Staff tried to tailor the challenge to the child's needs, mixing the relevant foods with a food that the child enjoyed and encouraging parents to let their child have a nap in the middle of the challenge if they were tired. If the staff member or parent noticed signs of a reaction (e.g. hives, lip or eye swelling or wheezing)

then the child was treated with appropriate medication (usually oral antihistamines) and the challenge was discontinued. At the end of the challenge parents were given advice about continuing to give or to avoid the food at home and were 'discharged' home with advice to contact the staff if they had any questions.

5.6 Conclusion

In this chapter I provided a background to food allergy and outlined the immediate and wider context in which the RCTs were conducted. I also provided an overview of the RCTs that were used as case studies for the research and described the parents and staff who agreed to participate in the interviews and observation. My rationale for this was twofold. Firstly I hoped to help the reader build up a picture of the setting in which I conducted the fieldwork. Perhaps more importantly I hoped that the reader would gain an understanding of the context in which the parents and staff made decisions and went about the activities that participation in the trials required. These descriptions provide an initial context that is developed further in the next three chapters, the results chapters.

In presenting the findings I follow the ethnographic convention and thus interpretation of the results is presented alongside the findings rather than at the end of the results chapters as is more usual in other research traditions. The first of the three chapters explores recruitment to LEAP and EAT.

Chapter 6: Benefit and equipoise: recruitment to LEAP and EAT

LEAP and EAT ostensibly examined the same research question: whether early introduction of allergenic foods is a more effective means of preventing children developing food allergy than delayed introduction. LEAP explored this question with regards to one food (peanuts) in infants who had eczema or egg allergy, whilst EAT examined the effect of early introduction of six foods (milk, egg, peanut, sesame, fish and wheat) in the general infant population. Both trials were RCTs in which 50% of children, the intervention groups, introduced the trial foods immediately following enrolment, earlier than the DoH recommended. The other half, the control groups, followed DoH advice and delayed the introduction of the foods for a specific time period.

Despite their many similarities, recruitment to the trials was quite different. LEAP finished enrolling 640 children within 19 months, ahead of the two-year target set prior to recruitment commencing. As Elsie described, this surprised many researchers:

No one expected that it would be recruited, um, on time, let alone six months early

[Elsie, Staff 01]

EAT aimed to enrol over 2000 infants. Although the original protocol allowed postnatal recruitment of young infants, the trial was initially designed to recruit the majority of participants antenatally. This was considered the most rigorous design, allowing the prospective investigation of factors that may confound the intervention³² prior to and after birth. However, accrual to the trial was slow, and 6 months into the recruitment period a decision was made to shift the focus of recruitment and target parents

³² Factors that were considered potential confounders to the intervention included maternal diet during pregnancy and the early life of the infant, maternal use of medications such as antibiotics during pregnancy, and use of medications in the early life of the infant (e.g. antibiotics, topical creams for eczema).

postnatally, accepting it would not be possible to prospectively explore the influence of antenatal factors on the primary outcome. Accrual rates improved, but in the following three months the number of enrolled participants still did not meet the targets. At this time there were concerns whether recruitment to EAT could continue under the existing funding arrangements, as recruitment was unlikely to be achievable within the budget that had been allowed by the funders. Amelia explained that it was only because the children that had already been recruited were noted to be at a higher risk of developing allergy than the general population that the funders felt able to continue with the trial. This higher risk population meant that the power to detect differences between the groups was increased and thus the number of participants needed could be reduced from 2000 to 1302 children. This sample size was thought to be achievable by the investigators, funders and steering committee, a belief that proved to be correct.

My experiences of working as a research nurse and the gaps identified in the literature raised several questions regarding recruitment. What informs parents' choices about whether to enrol their children in research? From where do they draw their knowledge to make their decisions about participation? In addition to parental views and decisions, what other factors are relevant to recruitment to non-therapeutic paediatric trials? I explore these questions using Bourdieu's (1977) theory of practice, examining the influence that is exerted by differing fields³³ of practice, the opportunity for individuals to acquire and exchange useful resources or prestige (in Bourdieu's terms, capital), and the habitus (values, viewpoints and dispositions) of those who are directly and indirectly involved in trial recruitment. I also consider whether parents' recruitment decisions

³³ Throughout the results and discussion chapters, where I refer to a 'field' I use the term in the Bourdieusian sense, to represent both the area where social activity takes place and the network of relations between individuals who produce the social activity (Bourdieu 1990), rather than a more generic use of the term.

reflected Titmuss' (1970) suggestion that participation in prosocial healthcare activities stems from '*a sense of obligation, approval and interest; some feeling of inclusion in society; some awareness of the need and purpose of the gift*' (p.238) or whether they more closely related to Bourdieu's (1977) view of exchange as a practice that allows the advancement of one's own position.

Five broad themes were identified during data analysis: protecting children from harm; views of research; whether the trial was beneficial; randomisation and perceptions of equipoise; and trial manageability. These themes are indicative of parents' thought processes when they decided whether or not to enrol their children in the trials. As I go on to show, these thoughts were influenced not only by parents' previous experience and knowledge, but also by the trials' staff, the trials' designs, and the background against which the trials were being conducted, including the need for and availability of healthcare and the prominence of specific infant feeding practices. In presenting these findings I start with a theme that underpinned many of the decisions that were made by parents and staff: protecting children from harm.

6.1 Protecting children from harm.

The aim of non-therapeutic RCTs such as LEAP and EAT is to uncover the best way to protect populations from the risk of the harm that diseases can inflict and, where possible, to reduce the societal costs that result from ill health. It seems incongruous, therefore, that those who take part in such trials may also be exposed to risk. These risks involve both the unknown effects of the (often novel) interventions that are being trialled and, as history has shown, the potential for exploitation by those in positions of power. For these reasons it is clear to see how a decision to take part in research may not be easy to make, and will depend upon perceptions of these risks.

As I discussed in the previous chapter, society considers that parents must seek out and protect their children from a multitude of hidden threats that might affect their health or wellbeing, a view that reflects Beck's (1992) notion of a 'risk society'. Beck argued that risk is a concept of the modern age: the modern 'reflexive' society has a heightened awareness of risk and desire to minimise risk exposure. He also suggested that individuals become '*active [in trying to understand and minimise risks] today to prevent the problems of tomorrow*' (p.34). These sentiments were evident in the data; parents placed substantial importance on protecting their children from harm and their discussions in this regard reflected the moral discourse that is central to the parenting field (May 2008; Francis 2012; Gillies 2012). Parents described protecting their children from the harms of trial participation or general ill health in terms that reflected being a 'good parent'. As will become evident throughout this thesis, this view was underpinned not only by their own values, but also by the prestige, or, in Bourdieu's (1986) terms, the symbolic capital, that could be accrued or lost, when, as they deemed they would be, their parenting abilities were assessed by others.

Two groups of HCPs were involved in recruiting children to LEAP and EAT. The first group were the researchers. As most children were recruited using an indirect means, such as a flyer sent to their home addresses, the researchers were often the first point of contact for parents considering their child's participation. The second group were HCP who were in contact with potentially eligible children, with whom the researchers collaborated. These HCP (henceforth referred to as HCP collaborators) including paediatricians, midwives, health visitors and general practitioners, worked in healthcare settings outside of LEAP and EAT but also had the ability to influence trial recruitment. As I go on to

discuss in later sections, both groups of HCP justified the decisions they made about recruitment in terms of the potential for children to be placed at risk of harm.

Parental and HCP concerns about the potential for children to be placed at risk of harm had a patent influence on recruitment to LEAP and EAT. These concerns reflected the risk that food allergy offered to the lives of children and the risks of taking part in the trial. Parents thought carefully about the risks of participation, suggesting that they *'wouldn't have put [their child] in just anything,'* [David L8F1³⁴]. In attempting to minimise the risk of harm for their own children and children more generally, parents and HCP considered a variety of issues. These are discussed throughout the remainder of the chapter, after I describe differences that were evident in the data between fathers' and mothers' views of the risks of trial participation.

6.1.1 Difference between mothers' and fathers' views of the trials

When I asked LEAP and EAT staff to talk about the reasons parents gave for declining an invitation to take part, staff from both trials told me that mothers often cited paternal refusal. Despite mothers initially expressing enthusiasm for the trial, during subsequent conversations they would say that, although they were keen to participate, their child's father had concerns and so they had decided not to take part. Although the staff could not be sure whether this was *'a polite way of saying we're not interested in your study'* [Oliver, Staff 02], conversations with fathers themselves and the frequency with which this reason was cited led the staff to believe that fathers did have more concerns about participation than mothers.

Information gathered from parents corroborates the staff views that fathers were more concerned about the risk of harm than mothers. This was not universally the case. Two of

³⁴ These codes refer to the trial (LEAP or EAT), interview number, relationship of the interviewee to the child (Father or Mother) and randomisation group (Intervention or Control) to which the child was assigned.

the fathers who participated in interviews described being more positive about their child taking part in the trial than their wives, and several parents said they had been equally enthusiastic. However, there were a good number of instances where parents told me that the father's initial response to whether they should enrol their child in LEAP or EAT was a negative one. Although fathers sometimes felt uneasy about subjecting their children to painful procedures such as blood testing, their greatest concerns reflected the risks of participation, particularly that their child might experience a life threatening reaction as a result of taking part. Tom discussed this during a joint interview with his wife Rosie:

I think that I probably had more concerns, didn't I? [...] ³⁵ introducing foods that I thought could be harmful, like the peanut butter and peanuts and things like that at an early stage [Tom, E55F1]

The following excerpt of Tom and Rosie's interview helps to explain why fathers were sometimes more concerned about their child's participation than mothers. In this excerpt they describe the process of their initial decision-making and their discussion captures the essence of several other interviews. Mothers usually made the initial contact with the trial staff as they were often at home on maternity leave with their young infant, and fathers felt ambivalent about reading large amounts of information in their spare time, but unable to make a decision without a detailed knowledge of the trials:

Tom: I think from my perspective if I'm given information, I read it and make a decision on it then, then that's fine. But because I'd left it to Rosie I didn't feel like I knew enough about it. I was questioning it more.

³⁵ [...] denotes the omission of small portions of text.

Rosie: I did keep pushing it [the information] your way but you're preoccupied, [Tom begins to protest], but you are preoccupied with other things like work, obviously, and stuff.

Tom: I think if I'd been directly involved from the outset, or had the interest from the outset I'd have agreed to it sooner and with less reservations.

HF: Did you ultimately read it [the information sheet] or did you, was it more just discussion?

Tom: I think I did read it in the end didn't I?

Rosie: Yeah, I think you did. I eventually said [strict voice] 'will you just read it and make a decision'. Cos I was very much, I, I did push you into it, didn't I?

[Rosie and Tom, E54MI & E55FI]

As this conversation illustrates, fathers' concerns were often alleviated once they found time to read the information and/or had detailed conversations about what participation would involve. As is also evident from their conversation, this required the mothers to persist in their endeavours to obtain a positive decision. Alison, who enrolled her daughter in LEAP, was one of several other mothers who told me that they had taken the time to convince their husbands:

Of course then I had to persuade my husband [...] he was much more concerned so I almost had to persuade him that there wasn't a risk [...] his immediate reaction would be to say, you know, if the government says this then why, why give her peanut? She might have an anaphylactic shock or whatever. And you know my answer to that is, if you want to give them peanut, why not do it in a hospital?

[Alison, L6MI]

When I asked Alison why she had taken the trouble to convince her husband she told me that she felt his concerns were unfounded. She personally could not see why they should not take part and, as she felt that the trial was answering an important question, she thought it was worthwhile trying to persuade him.

Although it seems that fathers were more concerned about the risk of participation than mothers, there may also be another explanation for their differing views. This is also highlighted in the previous excerpt of Tom and Rosie's interview, when Tom mentions that he has less interest in the trial. Decker et al. (2008) argue that men may be less motivated by the potential to help others in society and more motivated by the opportunity to help their own family, and there is evidence of this view in data collected for this study. As was the case for Tom and Rosie, mothers who had no concerns about their children's health often told me that fathers saw fewer benefits and were more concerned about the risks and logistics of participation than they had been. Furthermore, in two of the EAT interviews where both parents were interviewed together, discussions about why they had enrolled their children in the trial predominantly reflected the potential to benefit others in society. Towards the end of the discussions I asked the parents to summarise by independently giving me their top two or three reasons for taking part and by rating these reasons in terms of their priority. In both interviews the mothers' and fathers' responses were similar to each other in terms of their motivations, but their rating of these differed: fathers' prioritised the potential to benefit their child because they would receive a health check from a paediatrician, whilst mothers placed helping future generations of children at the top of their list.

Whilst maternal and paternal views of their child's participation in LEAP and EAT differed, the relatively small number of fathers who were interviewed and the disparity in the

number of parents who accepted and declined the invitation to enrol their children in the trials means that it is difficult to know for certain whether these differences were the result of gender. What is clear though, is that parental views of research *per se* were important for recruitment.

6.2 Views of research

In Chapter 1 I described how the healthcare community's concern about whether it is ethically acceptable to enrol children in research had now been resolved and it is generally agreed that in areas where the evidence base is lacking, research that involves children is both acceptable and necessary. The data gathered for this study suggest that the general public do not necessarily share this view. Contributors to the online discussion forum expressed concern that any research could be conducted with children who were unable to provide consent, using terms such as 'experimentation' and 'unethical' to convey these views. Those who expressed such views suggested they would not enrol their children in research.

Parents who took part in the LEAP and EAT expressed more positive views of research, a subject I will explore in greater detail in Section 6.4.2.1. However, they applied caveats to this positivity. Although Neil was the only parent who enrolled his child in the trial who described himself as being 'suspicious' of research, he also expressed a view that was common to other parents, that the field of medical research is a diverse one and that the level of risk offered by each specific trial is variable:

I mean horrible things do happen [...] there's a kind of funny line, because [research] covers a million things, you know? A phone call a month, of course that's fine. An injection a month, woah, you know?

[Neil, L31FC]

Pickersgill (2011) argues that improving the public's understanding of research is important for encouraging their engagement in trials and it certainly seems that LEAP and EAT parents' drew on their knowledge of research when assessing whether they should take part in the trials. The relevance that parents' views and experiences of research had on recruitment in LEAP or EAT means that it is unlikely to be coincidence that, as Chantler et al. (2007) also found, many parents who had agreed to their child's participation had medical or scientific backgrounds. As Bourdieu explains, '*when the habitus finds itself as a fish in water, it does not feel the weight of the water and takes the world about itself for granted*' (Wacquant 1996 p.216). Thus the habitus of parents with medical and scientific backgrounds perhaps predisposed them to take part. Participation in the trials did not seem out of the ordinary because they were already familiar with the principles and language of research and with the safeguards that are required before trials can be conducted.

Central to both parents' views of research, and of their assessments of whether they should enrol their children in these specific trials were judgements about the trustworthiness of the researchers. As I show in the next section, these judgements were important for successful recruitment.

6.2.1 Trustworthiness of the researchers

The indirect means of recruiting families meant that most parents had no previous relationship with the LEAP and EAT researchers. Parents often told me that, when deciding whether they should enrol their children in trial, they considered the trustworthiness of those conducting the research.

The parents who I interviewed expressed predominantly trusting views of researchers in general, but, reflecting the history of the field of medical research, were discerning in this

trust. They recognised that there were some dishonest researchers and their assessment of whether the LEAP and EAT researchers belonged to this group took a variety of forms. Seeing references to the well known institutions that were conducting the research offered parents reassurance as to the researchers' likely motives. Lizzie was one of several parents who suggested that:

something like King's College London and you know they've got a name, they're not going to put their name to something [...] if they're not entirely sure it's going to go right. [Lizzie, L20MI]

Yet whilst the association of a respected name with the trial was comforting, parents were concerned that this could be forged. Neil was not the only parent who described taking time to substantiate the relationship by seeking out references to the relevant trial on the Guy's and St Thomas' or King's College websites. He explained that:

what we didn't want was some shonky outfit trying to promote a new something, coming along, renting a ward for a month. [Neil, L31FC]

As other studies have also found (Mazzocco et al. 1999; Taylor and Kass 2001; Woodgate and Yanofsky 2010; Shilling et al. 2011), parents who had a prior relationship with the trial staff seemed to find the decision about whether to take part easier to make than those with no such relationship. Sally was invited to enrol her son in LEAP when she saw one of the trial investigators, who held a joint academic and clinical post, at a routine clinic appointment for her older daughter. She explained how their previous relationship influenced her decision to participate:

I had been in contact with him for a couple of years, um, and had liked him, and I'd thought, you know, he, he'd been good with [my older daughter], and so him suggesting it I guess had more influence.

[Sally, L9MI]

As this quote illustrates, parental opinions of the character of the researchers offered reassurance as to their likely motives, a notion that was extremely important to parental perception of the researchers' trustworthiness. Regardless of their previous relationship with the trial staff, those who took part, or who wanted to take part but were prevented from doing so for logistical reasons, described being reassured by the willingness of staff to answer questions, their openness about the risks of the trial, their friendly manner, and the professional look of the documentation. All of these aspects and particularly their interaction with the staff led parents to believe that the staff would share the their values that the best interests of the individual children must come first. In Bourdieu's (1990) terms, the habitus of the parents and staff aligned and this understanding had a positive influence on recruitment. Although Rebecca took her son to his first EAT visit with some trepidation, considering that she would leave if she felt uncomfortable with the setting or staff, on attending the unit she was both reassured and encouraged:

I really enjoyed speaking to [staff] and he was very open and, and easily answered my questions and was very personable. He picked [my son] up straight away and made a big fuss of him, which is really important to a mother that's quite nervous, obviously, about taking their child into a trial.

[Rebecca, E40MI]

Only one parent, who chose not to enrol her daughter in EAT, expressed a more negative view. Andrea told me that she had not been reassured by her pre-enrolment conversations with the trial staff. She felt that not all of her questions were well answered, particularly those relating to the risks of introducing food early, and this contributed to her decision not to enrol her daughter. It is not possible to know why her experience was so different from that described by many other parents. However, Cara, one of the staff, told me that despite providing training for new recruitment staff,

including mock telephone calls, they recognised that when a new member of recruiting staff started, the recruitment rates would reduce for a short while. She felt that this reduction reflected the time that it took for the staff to become adept at understanding parents' concerns and answering their questions appropriately.

Thus parents' views of research in general and their assessment of the trials' researchers' character was relevant to recruitment to the trials. However, these assessments did not only pertain to parents' views of the researchers' trustworthiness. As I describe in the following section, they also considered whom the researchers were aiming to benefit by conducting the research.

6.3 Who benefits?

As I discussed in Chapter 2, the potential for benefit is a key dialogue in both the empirical and theoretical literature regarding research participation. The data gathered for this study were no exception. Both parents and staff discussed the potential for benefit, although parents who declined participation³⁶ described fewer personal benefits from participation than those whose children did participate. Regardless of their final decision, when discussing why they considered participation in the trials, parents' motivations broadly revolved around the opportunity to derive benefit for their child and the opportunity to benefit society. As I will go on to describe in the following sections, these two scenarios were the manifestation of both parents' habitus, and of the philosophies and conditions of the wider context in which they were bringing up their children.

³⁶ With the exception of those who were unable to take part for logistical reasons.

6.3.1 *Benefitting society*

Parents' accounts reveal that acting in an altruistic manner was part of their habitus, a core value, often instilled by their own parents as part of their upbringing, which disposed them to take part in prosocial activities including donating blood and giving to charity.

Lesley, who enrolled her daughter in EAT, reflected that:

...anything that can help someone I'm keen to do. [Lesley, E34MIW³⁷].

Titmuss (1970) discusses the relevance of social responsibility for prosocial healthcare practices, and there is evidence that parents believed that they had an obligation to contribute to society. They described how trial participation was one way of fulfilling this responsibility, particularly when, as for Keira, a single mother who enrolled her daughter in LEAP, life circumstances meant they were unable to contribute in other ways:

Well I'm not working, I'm not contributing financially to society, so maybe I can do it indirectly, and that's my little [...] every little helps is my motto in life, and I thought, well this is another way that I can contribute. [Keira, L15MC]

Parents seemed to place great store by the bonds or networks within society from which valuable resources can be derived, i.e. on social capital (Bourdieu 1970), recognising that society in general and members of their family specifically, benefitted from these networks. With respect to research participation this was expressed both as a general acknowledgement of the progress of medicine and with reference to specific examples of the ways that they had benefitted from the altruism of others. The examples they gave included conceiving children through sperm donation and, for parents such as Sophie who enrolled her son into EAT, receiving medical care for themselves and/or their families:

³⁷ W denotes parents who withdrew their children from the trials.

I guess before I was pregnant I was never really ill [...] since I've been pregnant I've seen midwives a lot, had three ambulances, [my son has] been in the special care baby unit, so I kind of felt like I had my tax dollars worth but I would like to give something back for the care I've received.

[Sophie, E53MI]

As Sophie's quote illustrates, these views reflect the notion of gift exchange that was proposed by Titmuss (1970). The reciprocity that was evident in their discussions represented perceptions of a duty to give back to society as well as to take from it. By enrolling their children in the trials parents thus considered they would continue the 'relay' of altruism they felt was important in society.

Although parents discussed their desire to contribute to society, they were discerning about the manner in which they did this. As the following sections highlight, parents would only consider participation if they thought the trials' findings would make a meaningful contribution to advancing knowledge.

6.3.1.1 Is the topic worthy of investigation

Titmuss (1970) suggested that individuals donated blood because they understood the importance of doing so; *'the need and purpose of the gift'* (p.238). This view was evident in the data regarding recruitment to LEAP and EAT. Parents were clear that the medical community's lack of understanding about the causes of food allergy contributed to their decision to take part. Sharon, whose son was participating in LEAP, suggested that she would only enrol her children in trials of areas she considered to be under-researched, as these were the most worthy of her support:

I dunno if someone approached me over, hearing, say, whether or not I would [take part], because I think there's been a lot done on that already. I think it's the, the shady [less well understood] parts that need, that I would probably participate in. [Sharon, L11MC]

Titmuss (1970) also asserted that individuals' eagerness to contribute to society reflects a sense of belonging within that society. I asked parents whether they would still have taken part if the trials had used the same designs but had been investigating another condition such as migraine headaches. A few said that they would have considered participating, but many said that they would not have had the same motivation. This finding, particularly with respect to LEAP parents, is likely to reflect the firsthand experience that many had of having children or close family members with food allergy. They were willing to take part because they understood the difficulties faced by parents with food allergy: they were part of a 'food allergic society'.

Fewer EAT parents had a child or immediate family member with food allergy. Yet whilst they were not direct members of a 'food allergic' society, they had an unmistakeable empathy for food allergy sufferers and their families. Many parents had friends whose children had allergies, and understanding the difficulties they faced contributed to their view that the trial was investigating an important question. Andrew and Marianne explained how, after receiving the EAT flyer shortly after the birth of their second son, they immediately recognised the value of the trial. Andrew's godson had multiple food allergies and their knowledge of the difficulties that his parents encountered in their everyday lives provided the necessary impetus for Marianne to contact the trial staff and find out more about participation:

Andrew: Well [my godson] can die if he has egg products

Marianne: it's an absolutely huge, huge impact on their, on their life
[...] going to someone's house they, they have to ask
people to, you know, clear out egg products and things
[...] it doesn't make for a very easy life

[Andrew and Marianne, E42MC & E43FC]

In this excerpt they also discuss another factor that led many parents to consider that food allergy is a condition that is worthy of investigation: the risks to which food allergic children were exposed.

Lupton (1996) suggests that parents establish a '*cordon sanitaire*' (p.40) around their infants to ensure the food they eat is free from substances that could cause harm. Given society's heightened awareness of food allergy (Rous and Hunt 2004; Nettleton et al. 2009), many parents included foods that could invoke an allergic reaction, particularly peanuts, within this boundary. Some parents said that, given the rise in food allergies that was often reported in the media, they had been concerned that their children would be allergic. Even parents who had no concerns about their own child discussed the worry that the risks of food allergy could cause for parents of food allergic children, for whom there was an increased potential for the protective boundary to be breached:

Sophie: Is it something like 6% of the population have serious allergies, and if this can help stop, you know, I think, don't they die occasionally?

HF: Yes sometimes, probably four or five children a year will die of food allergy.

Sophie: Yeah, well if the study can save even one of those then it's an amazing thing to have taken part in.

[Sophie, E53MI]

Thus, for parents who had no personal experience of food allergy, or even a concern about their own child becoming allergic, it seems to be a sense of belonging to the field of parenting, the underlying philosophy of which reflected a need to protect children from harm, that led to their belief that research in this area was worthwhile.

As well as considering whether the topic was worthy of investigation, parent and staff views of whether the trials would produce meaningful results were also relevant to their perception of whether the trial was beneficial, and thus to recruitment to LEAP and EAT.

6.3.1.2 Will the trial produce meaningful results?

The importance that the trial investigators placed on producing meaningful results had a substantial influence on recruitment to EAT. A desire to design the most scientifically rigorous trial that would produce highly valid findings led the investigators to initially focus their recruitment efforts on the antenatal period so that antenatal data could be gathered prospectively. This decision was taken despite the concerns of one of the staff that trial accrual was likely to be poor. Ultimately this concern proved correct, and the EAT investigators recognised that it was pointless conducting a trial where the risk of bias to the findings had been strictly controlled if it was not possible to recruit sufficient participants to assess the final outcome. This led them to amend the protocol to recruit families postnatally, achieving a balance between scientific rigour and successful recruitment.

Parents were also concerned whether the trial would produce meaningful results.

Reflecting both their desire to contribute to society and the proxy nature of their decision, before agreeing to their child's participation they made an assessment of whether the findings would add to the current knowledge in a meaningful way. Parents' views in this regard varied. Lizzie and Kevin, who enrolled their daughter in LEAP, told me

that they thought a relative of theirs was unnecessarily concerned about giving her children foods that contained peanuts. They described seeking out information about what would happen to the results of the trials prior to agreeing to enrolment:

HF: What kinds of things were you thinking about I suppose, in terms of whether to take part or?

Lizzie: Um, I think it was more sort of how helpful is this likely to be? Um, what's, what's gonna happen to it as well, as in, will the study actually be helpful, sort of, to the wider public. Obviously if it's just going to sit, within medical sort of, um the medical sphere and not really break out, um [we might not have taken part].

Kevin: Yeah, would this research actually reduce the stress about peanut consumption?

[Lizzie and Kevin, L20MI &L21FI]

Many parents took the trial design into account in their assessments of whether the findings would make a meaningful contribution to society. During online discussion forum conversations, some contributors suggested that, by failing to include infants who had been given formula milk prior to six months, EAT's findings would be applicable only to those who had been exclusively breastfed. They considered that this was such a small percentage of children that the results would not make a substantial contribution to knowledge and thus that participation in EAT was pointless.

Parents who did take part in the trials believed that the designs would produce meaningful findings. During the interviews I asked parents whether the longitudinal nature of the trial had been off-putting, but most replied that actually the reverse was true. They believed that the longitudinal design was necessary for the final results to be useful and some even wondered if the trials should continue for longer than was being

proposed. Like several other parents, Christina explained that she would rather participate in a trial that involved some inconvenience but would lead to meaningful results, than one in which inconvenience was minimised but to the detriment of the quality of the findings:

[the length of the trial] was, sort of appealed more, um, because if it had just been now and then up to six months or something then I'd think, 'well they wouldn't gather much data like that'. Like, they wouldn't really be able to say whether [the intervention] helped or not.

[Christina, E41MC]

Another aspect of the trial design, the trials' inclusion criteria, was also relevant to parents' views that taking part in the trials would help to contribute to society.

6.3.1.3 Specific inclusion criteria

The trials' very specific inclusion criteria meant that less than 10% of UK children in the correct age range were eligible to participate in the trials [personal communication with PI 19th May 2011]. This limited the pool of children who could potentially participate which naturally influenced recruitment. It was necessary for trial staff to target a small group of families, and parents who were interested but whose children did not meet the inclusion criteria had to be turned away.

Although the narrow inclusion criteria meant that trial accrual was not always easy, they did have one advantage. Several parents told me that recognising that their child fell into a small group of eligible children had provided them with an additional impetus to take part. Reflecting their views that these specific trials should be conducted and their habitus that predisposed them to take part in research, they felt that, as the number of eligible participants would be limited, they could not assume someone else would participate. Lorna was one of several parents who explained that knowing that her

individual contribution could make a difference was one of the reasons she decided to enrol her son in the trial:

Almost like a moral obligation. There's so many babies that wouldn't be able to take part because, you know, they've had to be given formula [milk and are thus excluded from the trial], that, you know, if this research doesn't happen that's really sad. So if, if we can, then we should. [Lorna, E47MI]

As well as taking aspects of the trials' designs into account, parents also considered the likely motives of the researchers when assessing whether trial participation would make a meaningful contribution to society.

6.3.1.4 Motivations of the funders and researchers

Parents' views of whether the trial funders and researchers were conducting the trials to benefit society or for personal or commercial benefit were important for recruitment.

Several parents sought out information about the organisations that were funding the trials and explained that they would not have participated if the funders had been a drug company or organisation that manufactured formula milk for babies. They said that they would not wish to expose their children to research procedures if the findings would result in substantial financial gain for companies that they deemed to be more concerned with making money than with producing high quality research that would benefit communities.

I asked parents why they thought that HCPs conducted research and their responses were somewhat different from the views they held regarding infant formula or pharmaceutical companies. Almost all parents felt that HCPs who conducted research within the NHS did so to help advance knowledge for the good of society:

HF: Have you ever thought about why doctors and nurses conduct research?

Colette: Again, er, for the greater good I guess. You know and if you're, if you're really interested in a field of medicine I can only assume you want to develop it as much as you can, in, you know while, while you're able to.

[Colette, L4MC]

Jemima, who enrolled her daughter in LEAP, was the only parent to express a different view. Whilst she thought that HCPs conducted research to help advance knowledge, she believed that they also did so to help advance their own careers.

Contributors to the online discussion forums were less positive about researchers in general, their views bearing similarities to those expressed by Jemima. They suggested that any researcher could act not for medical advancement but for academic recognition or financial gain. These contributors voiced concerns about the exploitation of children and considered that they would never enrol their children in research. Although it is not possible to know definitively, these views may have been compounded by the case of Andrew Wakefield, a researcher who was deemed not to have acted in the best interests of the children who took part in his research (General Medical Council 2010), which was reported in the media around the time that the discussions were taking place.

Thus, for many parents, the decision to participate or even, on hearing about the trial, to seek out additional information to facilitate their decision-making, depended on whether they believed that the researchers and/or funders were primarily conducting the trials to benefit society or whether their motives reflected a desire to create personal wealth or obtain academic recognition. Most parents considered that researchers' motivations should be underpinned by societal rather than personal benefit. This view was evident

despite, as I go on to describe in the following section, parents' own motivations for enrolling their children in the trials reflecting a personal benefit model of participation.

6.3.2 *Benefitting their child*

Many parents told me that benefitting their child was their main motivation for participation. Parents often divulged this almost as a confession, telling me even before I had asked them why they had decided to take part, and frequently using the term 'selfish'. For example, when I asked Colette, whose son had multiple food allergies, what her thoughts were when she heard about LEAP:

I feel like it was purely selfish. Er, I talked to my husband about this whole research thing, before today, and I said you know, it was a selfish motivation in that we just wanted, I just wanted help.

[Colette, L4MC]

Like Colette, most parents who described their main motivation for participation as 'selfish' had children with allergic diseases such as eczema or food allergy. In Chapter 5 I discussed the dearth of allergy expertise within the healthcare field, and this appears to have positively influenced recruitment. Parents told me that a general lack of knowledge and expertise within their local health services left them feeling unable to adequately manage their child's health, and, for many, *'kind of desperate'* [Francesca, L12MC]. Their decision to take part reflected the central value of the field of parenting, which requires that parents do their best by their children and protect them from harm. On receiving the invitation to enrol their children in the trial parents recognised that participation would allow them to obtain expert help and advice that they felt that their children needed but that they had been unable to access via their primary healthcare practitioners. Sharon, whose son had severe eczema and multiple food allergies, was one of several parents for whom the invitation to participate offered relief and hope:

HF: And what were your first thoughts when you read it [the flyer she had received about LEAP]?

Sharon: Yipee-yo! Honestly I couldn't believe my luck. I just hoped that I could, he was in the category, of where they would take him on. [Sharon, L11MI]

Bourdieu (1986) argued that social capital stems from relationships, developed either consciously or unconsciously, that are useful either at the point that they are developed or at some point in the future. As trial participation permitted access to HCP who had the requisite expertise, parents deemed they would be tapping into a network of resources that would facilitate improvements in their children's health. Trial participation allowed parents to accrue social capital that helped them to be 'good parents' by protecting their children from the harm of poorly treated eczema or undiagnosed or poorly understood food allergy. Furthermore, many parents believed that, as these HCP were conducting research, they were likely to be at the forefront of their field and thus the advice they would receive would be the most up to date.

Parents who felt able to manage their child's health, viewed the opportunity access to expertise with less excitement. However, many still felt that having contact with a multidisciplinary team of paediatric specialists, a service not readily available via the National Health Service (NHS), was worthwhile. Although their desire for this help was less intense, enrolling their children in the trials still allowed parents to accrue social capital through their links with HCPs who may be able to assist them with their parenting role at some point in the future.

The potential for accessing experienced paediatric advice was one of the reasons parents contacted the trial investigators to find out more about participation. However, in the

absence of an immediate need for help the motivational pull of the expertise held less value for parents. As Jeanette, who had no concerns about her daughter's health prior to hearing about EAT explained, although she liked the idea that her daughter would receive a health check, this benefit was of lesser importance to her than her concerns about the effects of introducing solid foods early:

It would have been good for her, because, you know, we would know if she had any allergies, um, you know they, they were going to do health checks for her which would have been beneficial for her health [...] we would have been told if there were any problems. I really wanted that for her as well. Um so, so those were the, the pros really. And the cons obviously were it was going against the WHO guidelines, which I didn't really want to, so [I decided not to take part]. [Jeanette, E35MD³⁸]

In contrast, parents whose primary motive for participation was to obtain healthcare for their children placed less emphasis on other aspects of trial participation. Lily initially decided not to participate in LEAP because she was concerned that delaying giving her daughter peanut might be harmful. She changed her mind after her daughter's first allergic reaction, when her desire to obtain expertise that she felt was unavailable via the standard healthcare route became more important than other concerns, including the potential risks of the trial:

Lily: ...that's why we didn't initially enrol her because of this possibility that I might be causing more harm [if randomised to the control arm]

HF: So I guess what, what sort of tipped it over the edge into thinking it would be ok?

³⁸ D denotes parents who declined participation in the trials.

Lily: Because we really wanted her to be tested [to find out what had caused the allergic reaction] [...] whether she would be in the peanut avoidance [control arm] or, that wasn't so much of a worry because that was later on. Whereas the immediate worry after [the reaction] was we must figure out what it is [...] and so that was more important. [Lily, L1MC]

As I discussed in Chapter 1, that parents enrolled their children in the trials to obtain expertise is not a unique finding. However, the majority of studies that have found this to be relevant were therapeutic studies, where the notion of therapeutic misconception, i.e. that parents were unable to differentiate research participation from clinical care, is relevant (Ward 2009; Woodgate and Yanofsky 2010). In LEAP and EAT, where most parents had no previous relationship with the trial staff, they clearly recognised that their child was taking part in research; there was no therapeutic misconception. Rather, for them, the conditions of standard healthcare provision meant that they were unable to access the expertise they wanted for their children and trial participation could offer them access to this resource.

In Chapter 2 I described how ethical principles and legislation prohibit the use of incentives that may coerce families into enrolling their children in research, whilst also suggesting that it is desirable that they derive some benefit from participation. It is evident that the opportunity to obtain expertise for their child incentivised some parents to take part in the trials. Lily's scenario calls to mind questions about the voluntariness of participation. However, rather than being coerced by incentives offered by the trial staff, it was her situation, and in particular the lack of freely available paediatric allergy expertise in the field of healthcare, that led her to take part. This finding is corroborated by additional data. I asked other parents who had enrolled their children in the trials to

obtain expertise whether, if they had been able to access the care they had needed outside the trial context, they would still have taken part. The answer given by Mark, whose son was egg allergic and who heard about LEAP after watching a television news item about food allergy in which the trial was mentioned, was fairly typical of other parents in similar situations:

No. I used the LEAP study in that I would get the best for my son. Um it just so happened that the LEAP study and my objectives sort of complemented each other. But having said that, if we'd been to a consultant and he'd mentioned the LEAP study as well I'd have seriously considered it there and then as well. [Mark, L16FI]

Although parents described participating when, under different circumstances they might not have done, it does not appear that they felt coerced by their situation. All described weighing up the risks and benefits of participation before taking part and, as I will discuss in Chapter 8, they continued to participate even after their need for care resolved, despite understanding that they could withdraw from the trials at anytime.

Mark's quote also suggests that, as others have found (Mazzocco et al. 1999; Raynor et al. 2009), in the absence of an immediate need for help, direct approaches to recruitment may be more effective than indirect approaches. In his quote he also makes reference to an additional notion, reciprocity, which was also relevant to recruitment in LEAP and EAT.

6.3.3 *Reciprocity*

Although parents' motivations can be categorised, in their own words, as 'the greater good' (benefitting society) or 'selfish' (benefitting their child), few described a single motive. Rather, their reasons for participation seemed to fall along a continuum, with 'purely selfish' and 'purely greater good' representing the extremes. As Mark described, most hoped for a reciprocal relationship:

we didn't know what was going on with [our son] and we wanted answers, and that the LEAP study didn't know what was going on with other children and they wanted answers. [Mark, L16FI]

I described earlier that parents' discussions of reciprocity reflected Titmuss' (1970) notion of exchange: they considered that their participation in the trials would help others in the same way that previous generations' participation had helped them or their family. A more direct version of reciprocity was also evident, having more in common with Bourdieu's (1986) notion of exchange practices and of social capital. Most parents described the importance of there being '*at least a chance that [their child] would benefit*' [Joanna, L23MC] from participation because, as Jemima explained, their children were unable to contribute to the decision about whether or not to take part:

Because I was making the decision for my child I felt that it had to be for her benefit, not just for the benefit of society. [Jemima, L2MI]

Parents' recognition that research participation could be mutually beneficial was likely to have been influenced by the LEAP and EAT investigators, who discussed both benefit to society and benefit to the participating children in their promotional materials.

Information appealed to parents' sense of altruism:

Your help can make a difference. Please consider becoming part of our efforts to halt the rise in food allergy [EAT Flyer]

whilst also making reference to the specialist services that were available:³⁹

Children evaluated for the study will receive allergy testing and dietary advice from paediatric allergy specialists. [LEAP Flyer]

³⁹ Both trials informed parents that the travel expenses that they incurred would be met, but LEAP did not mention that children would also receive gifts at their trial visits.

EAT initially chose not to include a description of the potential benefits of participation in their promotional materials because they were worried that they would be inundated with responses and, owing to limited resources, unable to manage. However, midway through recruitment they modified their website to include similar text to that described in the LEAP flyer, hoping that accrual rates would be enhanced by highlighting the benefits that participation could afford. Ed explained that this was in response both to concerns about rates of recruitment, and to suggestions from participating parents that the trial was '*selling itself short*' [Ed, Staff 04] and that the benefits of participation should be described in their promotional materials. This suggests that, although parents' hope for personal benefit may have been influenced by the approach that the investigators took to recruitment, they also saw for themselves the benefits that participation in the trials might afford.

Staff in both trials explained that, although a reciprocal arrangement was acceptable, they must also abide by ethical codes of conduct. The staff were aware that, in light of the poor allergy healthcare provision, their expertise might act as an incentive to participation. This knowledge led them to take additional steps to ensure that parents were aware of the purpose of the trial, the burdens and risks of participation and had thus made an informed choice about whether or not to take part rather than simply agreeing to take part to obtain the expertise they desired. They explained that it was not always easy to do this, as turning away parents who wanted to take part when trial accrual was slow seemed contradictory. However, they felt that their responsibility to ensure that parents had provided informed consent was greater than their need to recruit sufficient trial participants.

Thus it is clear that both societal and personal benefit were relevant for trial recruitment. The presence of both models reflected parental knowledge and beliefs about food allergy and the lack of allergy healthcare expertise outside the trial context, the researchers' conduct, and the specific conditions of the wider fields of healthcare and parenting. Whilst both models were evident, the responsibility that parents felt to protect their children meant that personal benefit had a greater motivational pull than societal benefit. Furthermore, whilst parents habitus predisposed them to take part in research, it was a sense of inclusion within society, be it a 'food allergic society' or the parenting field that led them to take part in these specific trials; many said that they would have been unlikely to take part in the trials had not been investigating food allergy, a condition they considered to be important.

Whilst it is evident that societal benefit, personal benefit and reciprocity were relevant, they represented only one part of the mesh of factors that influenced recruitment to LEAP and EAT. The randomised nature of the trials also played a significant role in trial accrual.

6.4 Randomisation, equipoise and dominant cultural values

LEAP and EAT were both RCT and thus parents were not able to choose the group to which their child would be allocated. This was explained in the written information given to parents considering their child's participation. It was also discussed verbally during the telephone conversations that took place between the trial recruiters and most parents before they attended the first trial visit. During my observations I noted that it was also emphasised to every parent at the first visit, before their child was formally enrolled on the trial:

Steph asked the parents whether they understood that the study was randomised and that they could go into the consumption [intervention] or avoidance [control] groups. They said that they did but that they were hoping to go into the consumption group. Steph said it was ok to have a preference but confirmed whether they would be happy to continue if they were allocated to the avoidance group.

[Field notes, 3rd February 2011]

The staff told me that, during their pre-enrolment conversations, parents often said that they had a strong preference for one of the intervention arms and thus, because they could not accept randomisation, they would not take part. Three families who chose not to take part in EAT expressed similar views during the interviews. Jeanette told me:

I did say to the lady on the phone, if I could guarantee that I would be in the, in the group that was exclusively breastfeeding with no introduction of foods then I would happily stay in the study [attend the first appointment that she had provisionally scheduled prior to reading all the information – she had not provided formal consent for her daughter’s participation]. But she said ‘oh you know I, we can’t guarantee that, obviously, you know because it’s a random study’ and I understood that.

[Jeanette, E35MD]

Parental willingness to accept randomisation reflected their perceptions of equipoise, a notion that I mentioned in Chapter 1. As I go on to show, whether parents and HCP collaborators believed that there was uncertainty regarding the relative superiority of the two interventions was important for trial recruitment.

6.4.1 The trials’ hypotheses and equipoise

All parents received written information explaining the trials’ questions, and staff described how they had spent time explaining the trials’ hypothesis to parents:

We really did spend a lot of time explaining the concept of tolerance, how allergy takes place. People wanted to know ‘well if you don’t eat, how does it take place?’ And then I would spend a lot of time explaining how it might happen through the skin, but we don’t know [...] actually treating families or participants as equal partners, intellectually explaining to them better what happens, what is interesting about this [...] that might bring them on board more easily. [Oliver, Staff 02]

My observations of the clinical trials unit corroborate this and I recorded many instances of staff and parents discussing the rationale for EAT. Data from parent interviews also lend support. Previous studies have found that research participants have limited understanding of the aims of the trials, or sometimes even that they are participating in research at all (Kodish et al. 1998; Rothmier et al. 2003; Tait et al. 2003; Chappuy et al. 2010). Yet all of the parents who I interviewed talked about their participation in such a way that it was obvious that they had a good understanding of the research, including the trials’ hypotheses. This is illustrated in the following excerpt of an interview with Lyndsey, who enrolled her son in EAT:

HF: Um and I guess what were your thoughts [when you first heard about EAT]?

Lyndsey: I thought actually it’s quite a fascinating study, and when I spoke to my husband we discussed it and we, we figure the hypothesis that early introduction will actually stop um, allergens forming, um if, if it is true, if it’s proven true then we’re actually doing [our son] a big favour by doing it. [Lyndsey, E39MI]

When considering whether to enrol their children in the trials some parents felt that there was uncertainty as to which of the two interventions was likely to prevent children developing food allergy and were thus happy to accept randomisation. Other parents

held such strong beliefs that the trials' hypotheses were correct and thus had such a strong preference for the intervention that they chose not to take part because they did not wish their child to be randomised to the control arms of the trials.⁴⁰ Despite strongly favouring the intervention arm, another group of parents did agree to take part. I wondered whether these parents would have withdrawn if their child had not been allocated to their preferred group but this did not seem to be the case. Rather, their willingness to take part reflected both their desire to protect their children from harm and the societal view of food allergy that I discussed in Chapter 5, where certain foods, particularly peanuts, are viewed as potentially harmful. Sophie told me that, after hearing about the trial, her husband Alex felt strongly that introducing their son to solid food at an early age was the correct way to prevent him from becoming allergic. She had no particular reason to believe that her son would have food allergies but, like others, particularly first time parents, she did not want to introduce him to foods that could cause a life threatening reaction at such an early age without the support of a medical team. Sophie explained that, despite him favouring the intervention arm, she convinced Alex to agree to their son taking part because participation would provide a 50:50 chance of obtaining the support she required to wean their son in the way that he felt was right:

Alex only wanted us to do it if we were in the early introduction [intervention] group, but I said to him we might as well do it because I'm not going to have the nerve to, for example, introduce peanut before six months [...] us doing the study [and being randomised to the control arm], we'll be in exactly the same position [as] if we don't do the study, [but] if we're in the trial group then we'll be in the group that you want.

[Sophie, E53MI]

⁴⁰ I explore how parents' views of equivalence between the two interventions were formed in section 6.4.2.

The trials' hypotheses were not always met with such enthusiasm. Contributors to the online discussion forums expressed deep concerns about EAT, considering that babies who were less than six months old should not be given solid food for a variety of reasons, of which concerns about allergies were only one. Parents who I interviewed and who chose not to take part in the trials expressed similar views. In their joint interview, Georgie and Gareth told me that, owing to a family history of gastrointestinal disorders, they were concerned that giving their son solid food before six months may predispose him to such conditions. For them, and for Jeanette and Andrea, a lack of equipoise in favour of the current policy of infant feeding meant that they felt unable to accept randomisation and thus could not take part in EAT. Only one parent, Neil, did agree to his daughter's participation (in LEAP) despite having a strong preference for being in the control arm. He said that he enrolled her in LEAP because he wanted access to the expertise that the trial staff could provide and was honest in admitting that, had his daughter been randomised to the intervention arm, he would have immediately withdrawn her.

It is evident that parental equipoise had a substantial influence on their willingness to enrol their children in the trials. As Howard et al. (2009) also found, HCP collaborators' views of equipoise were also relevant to recruitment because, through their relationship with families of potentially eligible children they could influence trial accrual. These HCP collaborators were not interviewed for this thesis, but the accounts of LEAP and EAT staff were consistent regarding the views they expressed. Their reports were substantiated by parents who independently described hearing similar opinions from HCP with whom they had contact. LEAP and EAT staff told me that, although some HCP collaborators considered the trials' questions interesting, the hypotheses valid, and were happy to

assist with recruitment by referring eligible families to the trials, others met requests for collaboration with resistance. The staff said that many of the HCP collaborators who were approached to assist with recruitment held strong opinions that the current policy of infant feeding was correct, that the trials' hypotheses were flawed and, in the view of some, harmful; they were clearly not in equipoise.

Whilst these views were expressed with regard to LEAP, the staff felt that they were mentioned more frequently and with greater passion with regards to EAT. Staff explained that HCP collaborators who voiced such opinions said that they would not inform the parents of eligible infants about the trial and some placed barriers to trial staff recruiting from their institutions. Ed felt that these barriers may have contributed to the initially low rates of accrual to EAT and certainly contributed to the decision to amend the protocol and recruit postnatally rather than antenatally. He told me that, when it became apparent that using two hospital sites was not achieving adequate rates of accrual, the investigators considered approaching two additional hospitals. However, informal information that HCP from one of these sites planned to strongly object to their department's collaboration contributed to the EAT investigators' decision to abandon this method of recruitment.

Because HCP collaborators were not interviewed for this thesis it is not possible to know how their views of equipoise were constructed. However, almost all parents who I interviewed described having a preference for one of the interventions prior to taking part, even if this preference was not strong enough to prevent them from accepting randomisation. There is evidence in the data that, when considering whether there was equivalence between the two interventions under trial, parents drew on a variety of sources of evidence.

6.4.2 *Sources of evidence and equipoise*

I wondered why some parents and HCPs were in equipoise whilst others seemed to favour either the trials' hypotheses or the current policy. Previous studies have shown that the way that a trial is presented to participants influences their views of equipoise (Donovan et al. 2002; Paramasivan et al. 2011) and the way that LEAP and EAT staff presented the trials may well have been relevant. Whilst, in the discussions that I observed between parents and staff, staff tended to emphasise that there was uncertainty as to the best approach, the written information was somewhat less unbiased:

The reason for this study is that there is uncertainty as to when is the best time to introduce solid foods, and in particular when to introduce the common allergenic foods, as the best way of preventing your child developing food allergies [...] Numerous studies spanning several decades have attempted to achieve a reduction in food allergies, including peanut allergy, by eliminating foods such as peanut, egg and milk from the diet of infants and mothers during pregnancy and whilst breastfeeding. These studies have had little success in reducing the frequency of food allergy. One possible explanation for the failure of these studies is that the elimination of foods was not properly achieved. An alternative reason may be that avoidance is not the best strategy and that the early introduction of peanut may actually protect against the development of peanut allergy. There are countries in the world where children eat peanut foods early in life and incidence of peanut allergy in these countries is low e.g. Asia and Africa. This is also true in Israeli children where our study findings reveal that eating a high dose of peanut protein early is associated with a low prevalence of peanut allergy. [EAT informed consent document]

As is evident in this excerpt, although uncertainty was mentioned, the substantiating information seemed to favour the intervention, suggesting that the early introduction of solid food might be superior to the current practice.

Whilst the bias that is evident in the written information may help to explain why parents felt that early introduction of solid food was correct, it does not account for parents who favoured the current policy. The sources of evidence that parents used to form their opinions appear to have had an important role to play in parental equipoise. Three sources of evidence were distinguishable within the data relating to parental perceptions of equipoise: research; policy or governmental guidance; and the experiences of friends or personal experiences.

6.4.2.1 Research evidence

Many parents discussed the relevance of research evidence informing their decisions and practices, a finding that is likely to reflect the medical and scientific backgrounds that a third of them possessed. However, even parents without obvious scientific literacy clearly articulated the value they placed on research informing practice, particularly when they felt that their family had either benefitted from research or had been put at risk by a lack of research. Georgie, a full time mother who left school at 16, described how previous failures to conduct research might have been detrimental to her son:

I have, um, inflammatory bowel disease, and I'm on a medication, and I kept asking, would it harm him [if I took it whilst I was] breastfeeding? [...] but they said the medication I'm on, they had no research on it [...] I thought [the lack of research] would be because it was dangerous for him, but it's because nobody had researched anybody under six months. Which makes you think, 'well it needs to be done'. [Georgie, E36MD]

The importance that parents placed on research evidence, coupled with information from the trials information sheets which highlighted that the current policies regarding food allergy were not based on scientific evidence and that observational data suggested early introduction may be the correct method, often helped to convince parents that there was uncertainty as to the best way to prevent children from developing food allergy.

However, as I described earlier, some parents felt that the observational data was sufficient to convince them that early introduction was superior and thus were not in equipoise. As I will discuss in the following section, they often drew on additional sources of evidence in this regard.

6.4.2.2 Governmental policy guidance

Parents also discussed using governmental and organisational advice or guidance to underpin their views and practices. Some placed little store by such guidance, citing examples of how frequent changes lessened their faith in the advice, with several referring to changes to the DoH policy regarding the age at which children could be given peanut. Sally, who enrolled her second child in LEAP, became less trustful of policy after her first child had an anaphylactic reaction to milk, an occurrence that was more shocking to her because she had diligently followed the guidance that she believed would have prevented this from happening:

so it was a huge surprise to find out that [my daughter] was allergic to milk, when I'd breastfed her and, you know, done everything you were meant to do.

[Sally, L9MI]

Parents who had not had such experiences were more trusting of guidance, and particularly of guidance produced by high profile organisations such as the DoH or WHO, which they perceived to have the best interests of children at heart. The faith that

Jeanette had in WHO advice had a major influence on her decision not to enrol her daughter in EAT:

The World Health Organization recommends six months pure exclusively breastfeeding which is what I'm doing, um and they, they don't recommend introduction of foods earlier than six months, um and that was really the reason [I chose not to take part]

[Jeanette, E35MD]

Parental belief and trust in the policies of high profile organisations was important to whether they participated in the trials. Those, like Sally, who had little faith in the guidance felt able to take part in research that went against these policies. Reflecting the notion that the field of parenting is subject to outside intervention, others, like Jeanette, placed great trust in policy and chose not to take part. There was further evidence of this influence in the online discussion forum data. Some contributors to the forums seemed to believe that there was uncertainty as to the best way of preventing children from developing food allergy. However, they considered that if they made the 'wrong' decision about participation and their child became allergic, they would feel less guilty if they had followed the governmental guidance than if they had 'experimented' with their child. This somewhat contradicts Mills et al. (2003), who found that participant equipoise was crucial for recruitment. The findings of this study suggest that, if parents feel unable to act against existing guidance, participant equipoise may actually lessen their willingness to take part.

6.4.2.3 Personal experience

Although parents drew on research and policy evidence, it was their personal experience that seemed to be the most important in forming their views of the trials' interventions and thus of equipoise. The experiences of some parents led them to consider the current

policy of avoidance of allergenic foods was correct. These parents used examples of how their own or their family or friends' children had been fed according to this policy and had not become allergic as evidence that the trials hypotheses were likely to be incorrect. Andrea, who chose not to enrol her daughter in EAT, cited just such a reason for non-participation. Her sister had followed the policy guidelines when weaning her three children and none had developed food allergy. She thus believed that avoidance of solid foods was likely to be the best way to prevent her daughter from becoming allergic and consequently could not accept randomisation.

Parents who agreed to take part in the trials often described how the trials' hypotheses struck a chord, fitting with their personal beliefs or experiences of the reasons children develop food allergy. Several parents who had grown up in non UK countries, particularly those from Africa, drew on direct experiences of the differences in the advice given regarding infant feeding. They felt that, in their home countries where there were no restrictions on infants' diets, food allergy was rare, whilst in the UK, where guidance cautioned against giving infants solid foods too early, food allergy was more common. As Ada, whose eldest son was participating in LEAP and who moved to the UK a month before he was born, described:

Where I come from we don't have all these allergies, we don't hear of it really, no. Cos they don't say don't eat peanuts, don't eat this, don't eat that, you know when you're pregnant don't do this. Over there you just, you hardly hear someone is allergic to anything [...] I'd had lots of peanuts and bananas [during pregnancy], because it's very, it's something that is [frequently eaten], really, you know, peanuts and bananas, where I come from.

[Ada, L22MC]

Drawing on these personal experiences, parents felt that the trials' hypotheses may correct, or at least were unlikely to be harmful, and were thus willing to consider participation.

Although parents used three sources of evidence to form their opinions, the reason that parents and HCP collaborators held such strong opinions regarding the trials hypotheses, and thus that so many were not in equipoise, seems to relate to differences between the field of the trials and the field of infant feeding practices.

6.4.3 *The trials' hypotheses and infant feeding policies and practices*

During the interviews parents described the great importance that they and the HCP who advised them placed on decisions about the diets of their infants. Parents believed that feeding their child was one of their major responsibilities, and their success in this regard was key to being a 'good parent'. As Jeanette explained, choices about feeding their children could have long-term implications:

I just think at this age you're building the foundation blocks for her whole, her whole health, you know? [Jeanette, E35MD]

LEAP had a limited influence on participating children's diets and although not all parents and HCP collaborators were in equipoise about the early introduction of peanut, the trial staff felt that the strength of this opinion was not sufficient to significantly hamper recruitment. However, not only did EAT have a much greater influence on infants' diets, but views of the relationship between the trials' hypothesis and current policies '*aroused very strong passions*' [Amelia, Staff 05]. There appears to be one main explanation for this. Although EAT researchers wanted mothers to continue breastfeeding and not to introduce formula milk before six months of age to avoid '*confounding the intervention*' [Amelia, Staff 05], many parents and HCP considered that introducing solid food before

this time would negatively influence breastfeeding and were thus unwilling to take part in or collaborate with the trial.

The extent to which the philosophy of field of infant feeding influenced recruitment was highlighted during the interviews with several LEAP parents. A conversation that I had with Nicole, whose second son was participating in LEAP, was typical of these parents' views. At the beginning of her interview, Nicole discussed her belief in the hypotheses that underpinned both trials, i.e. that consumption, rather than avoidance of foods, was the correct way to prevent food allergy:

when I was pregnant with, with [my son], my eldest, I was told not to eat peanuts during pregnancy and, being me, I actually specifically ate a teaspoon of peanut butter a week. [...] And I felt strongly that the guidelines that you're given at the minute [to avoid peanut], I don't think are quite right.

At the end of the interview Nicole asked me how the study was progressing and I told her that I had nearly finished interviewing parents and staff from LEAP and was waiting to start with EAT. She hadn't heard about EAT and asked me what it involved. Given her earlier positivity towards the goals of LEAP I was surprised by her reaction:

Nicole: Ooh, you see I wouldn't want to be involved in that [EAT].

HF: You wouldn't? Why?

Nicole: No I wouldn't have wanted to be involved with that, purely because I feel from, from being a parent, that weaning a child at four months is too soon. I just think it's, it's too early [...] I genuinely think that, that breast feeding, um, was enough for both my boys until six months, and weaning at four months, no. No I wouldn't have wanted to do that [Nicole, L24MI]

Thus, although Nicole considered LEAP's hypothesis to be correct and was happy to take part, when this interfered with breastfeeding, a practice that she held in high regard, her views of whether participation was acceptable were amended.

Bourdieu's (1977) concepts of capital and the field of practice are useful in exploring why HCPs and parents held such strong views regarding EAT. Their views seem to have been influenced by differences between the power possessed by those operating in the trials' fields and those operating in the field of infant feeding. At the time EAT was recruiting breastfeeding was afforded high status by many in society. Organisations such as the WHO and UNICEF placed great emphasis on exclusively breastfeeding infants until they were six months of age; UNICEF awarded prestigious 'Baby Friendly' accreditation to hospitals with a proven commitment to assisting mothers to achieve this goal. The DoH also eulogized that 'breast was best' via written advice that was provided to parents, the subtext of which was that mothers who did not exclusively breastfeed until their infant was six months of age might not be doing their best by their children:

breastfeeding is the healthiest way to feed your baby. [...] Your breastmilk is the only food designed for your baby. It contains everything your baby needs for around the first six months of life.

[Birth to Five: DoH 2009]

Media use of terms such as 'controversial' to describe scientific studies finding that infants who were not exclusively breastfed to six months of age had not been harmed,⁴¹

⁴¹ For example, this article was reported in the Independent Newspaper on 15th January 2011: Mothers besieged Internet forums and radio phone-ins yesterday to express their frustration at the latest scientific controversy about breastfeeding. In a review of existing evidence published yesterday, a team at the University of London's Childhood Nutrition Research Centre suggested that mothers should not follow official advice recommending that they exclusively breastfeed for the first six months.

and regulations prohibiting the advertising of infant formulae⁴² further emphasise the high status that was afforded to breastfeeding in UK society at that time.

Lee (2007) suggests that discussions about maternal choices about breastfeeding have a moral dimension. This view that was reflected in this study when mothers described both the importance that others had placed on them breastfeeding, and how they felt that their parenting abilities were judged based on their choices about breastfeeding:

[my mother in law] she's been quite sort of, you must breastfeed your baby, it's so good for them. [Eve, E32MR]

my personal experience of have, going through maternity and then postnatal with the NHS is that they are so, so rigid on this is the bible of, of you know, breastfeeding. This is how you should do it. Any deviation, um, you know, you're, you're made to feel like you're a really bad mother. [Lyndsey, E39MI]

Bourdieu (1986) argued that actors accrue symbolic capital, or prestige, by following the philosophy of the field within which they practice. As I described in Chapter 5, the field of parenting is no longer considered the sole domain of parents. Rather, parenting practices are heavily influenced by external guidance from professionals, including HCPs, who inform parents about, and promote their adherence to, the guidance that the Government consider parents require to bring up their children. At the time of recruitment, the philosophy or, in Bourdieu's terms, the shared habitus of the actors and organisations that were influential within the field of infant feeding reflected a view that exclusive breastfeeding was best for children. Thus, those within the field, particularly new parents who were entering the fields of infant feeding and parenting for the first time, could accrue significant symbolic capital by practising or promoting exclusive

⁴² The infant formula and follow on formula regulations 1995.

breastfeeding; by adhering to these policies parents were viewed as 'good parents'. Given this, it is perhaps unsurprising that a trial where the hypothesis suggested that prolonged exclusive breastfeeding may be detrimental to children⁴³ was viewed negatively by those in society who could gain substantial prestige from promoting or practising this method of infant feeding. Coupled with differences in the power available to those in the field of infant feeding (which had a long history, a shared international philosophy and could draw upon substantial resources) and those within the trials (which was trialling a new hypothesis within a local sphere and had limited resources), it is possible to see why there was a lack of equipoise regarding EAT's hypothesis and thus that recruitment was not easy.

Once parents were reassured that participation was unlikely to harm their child, considered that participation would be beneficial for either their own or other children and were prepared to accept randomisation, their perception of whether they could manage all the requirements that participation would entail helped them to make a final decision regarding whether to enrol their children in the trials.

6.5 Manageability

Parental beliefs regarding the manageability of the trials' activities were relevant to recruitment and their views in this regard were supported by parents' habitus, their deeply held values that they must complete the activities they had agreed to conduct. Parents discussed how, whilst understanding that they could withdraw from the trials at any time and finding this reassuring, they did not want to begin the trial unless they thought it was likely they would complete it.

⁴³ In terms of protection against allergic disease.

When considering whether they could manage participation, parents thought about the location of the trial site and their ability to manage the day-to-day activities. These are discussed in the following sections after I describe a broader issue of manageability that influenced recruitment: the assessments that funders and staff made regarding the trials' feasibility.

6.5.1 Feasibility

Prior to committing substantial resources to a large longitudinal trial, the PI and LEAP funders chose to conduct a one-year feasibility trial. During this time a small team of researchers explored avenues of recruitment, provided information about the proposed trial to local HCP who might collaborate with recruitment, and conducted focus groups with parents about the best methods of marketing the trial. By the end of this period the funders and PI were reassured that recruitment was likely to be achievable and LEAP was initiated. However, EAT had no feasibility period or pilot study. This was predominantly due to a lack of resources, but also reflected the quick accrual of participants to LEAP; the team were considered to have a proven track record of recruiting young infants to a trial. Some EAT staff suggested this lack of feasibility or pilot meant that problems with recruitment were not fully appreciated, resulting in the use of a recruitment method that may otherwise have been deemed unfeasible and thus a less efficient use of limited resources.⁴⁴ These staff stressed the importance of pilot or feasibility phases of trials, even if previous similar trials have been successful in accruing participants. However, two staff also mentioned that, had a feasibility period been undertaken, the trial might well not have been funded. They considered this would have been regrettable as, despite the

⁴⁴ The decision to begin recruitment antenatally was underpinned by a desire for a rigorous design as well as by the likely feasibility of the method.

struggles they had encountered during recruitment, they felt that the trial findings would make an important contribution to advancing understanding of food allergy.

6.5.2 *Location*

Parents considered several factors relating to the trials' location. The distance that would be needed to travel was one aspect. Although many parents lived in London a significant proportion came from further afield. Parents who did not feel that their children would benefit significantly from participation suggested they would not have travelled far to take part. For others, the importance that was placed on the research or on the benefits that participation might confer led them to travel long distances. Parents who took part in the interviews lived up to 260 miles from the research site.

Not all parents felt able to manage travelling with a young infant. Eve told me that she had really wanted to take part in EAT. She had a background of working in the NHS and felt that research was important and that EAT was investigating an interesting question. She also considered that the medical examinations her son would receive would be beneficial for him. She had booked her first appointment but, as the time grew nearer, she felt that the logistics of travelling 250 miles with a three month old baby for an hour long appointment were too great. She said that she contacted the trial staff to see if it would be possible to have the physical examinations performed at a site closer to home, or whether another solution could be offered, but was told that there was no alternative. She described being surprised at this and felt that the trial staff had not properly thought through the logistics of inviting families who were living so far away to participate in the trial.⁴⁵

⁴⁵ Some parents who had to travel long distances requested, or were offered, the opportunity to stay overnight in the 'patient hotel' at the hospital. Why Eve was not offered this service is not clear.

Ease of travel was also important to parents. Although some welcomed the opportunity to visit the attractions of London, for others, unfamiliarity with London and the need to use the London underground network with a small child made them think twice about whether participation was possible. Rosie was one of several parents who told me that they only felt able to take part because a family member or friend could travel with them to provide assistance on the journey:

just going with [my daughter] on my own would have been quite traumatic, getting down to London, I think. Because we're not London people, you know? It's the big smog and all that. [Rosie, E54MI]

Regardless of their final decision, several parents highlighted the difficulty of travelling with young children and those who lived further away recommended future trials opened local sites. When I put this recommendation to the LEAP and EAT PI he told me that, although he recognised that local sites would improve recruitment to LEAP and EAT, the financial resources and personal expertise that would have been needed for multicentre trials were prohibitive.

6.5.3 Ability to manage the day-to-day activities of the trial

The ability to manage the day-to-day trial activities was relevant to the recruitment practices and decisions of both staff and parents. LEAP and EAT staff were either fully employed to work on the trials or had protected time to conduct trial activities and thus were not required to fit recruitment activities around clinical commitments. Furthermore, both trials employed staff whose roles were dedicated primarily to recruiting participants, which, as Treweek et al. (2010) found, can positively influence trial accrual.

The availability of economic capital was also relevant to recruitment. LEAP was proportionately better funded than EAT and whilst, in response to direct questions, LEAP

staff said that they had never felt that a lack of resources had hampered recruitment, the same was not true of EAT staff. They described how their staffing levels, which reflected both the availability of funding and of experienced professionals, influenced the number and flexibility of the appointments they could offer. There was evidence in the data that these reduced staffing levels negatively influenced recruitment. Two parents who were interviewed for this thesis described being unable to participate because no mutually convenient appointments were available. The short window for which children were eligible for participation compounded this problem by reducing the length of time in which a mutually convenient appointment could be found.

The ability to manage the day-to-day activities of the trial was also important for parents. Many parents described thinking hard about the time commitments that participation would entail, not simply to judge whether they could fit participation around their daily commitments, but, reflecting the importance they placed on contributing to society, also to ascertain whether their participation would make a worthwhile contribution:

it wasn't so much, um, that I was worried about the time, like out of my day, I didn't feel like that, it was sort of [would I be able to] remember to do [the necessary activities]. [Christina, E41MC]

The 'routine' nature of the intervention, feeding their child according to a specific plan, positively influenced parents' decisions to take part. They perceived that taking part would not involve much additional work, as, regardless of trial participation, they would feed their children anyway.

Parents also considered whether they or their child would be able to cope with the intervention, drawing on previous experience regarding whether they would be likely to manage. As well as reflecting a desire to protect their children, these concerns also

reflected whether their participation would make a meaningful contribution to the study.

Talia told me that difficulties she had had establishing breastfeeding led her to question whether she would be able to take part in EAT:

For me, the side, the thing that was the issue about the food was the breastfeeding, would I, I think my concern was, what if I can't fully breastfeed him up to six months but I'm in that arm, then what would happen?

[Talia, E50MD]

LEAP and EAT staff also explained that one of parents' most frequent concerns about participation was whether they could manage to do what was expected and the consequences if they were not able to. They described frequently offering reassurance that they would provide assistance if it was needed but also highlighted how, exceptionally, practicalities may prohibit participation and families may not be able to take part despite wanting to do so. This is discussed in greater detail in the following chapter.

6.6 Conclusion

The data suggest that recruitment to LEAP and EAT was influenced not only by practical issues or by parents' views, values or characteristics, but also by the practices of the staff and the context within which the trials were being conducted. Bourdieu (1992) argued that practice is influenced by the interaction between differing fields of practice and it was evident that, in LEAP and EAT, recruitment was influenced by the fields of the trials themselves and also by the fields of medical research, healthcare, parenting and infant feeding. The availability of capital within the fields and the extent to which the philosophies of the fields were convergent, played an important role in recruitment.

The history of medical research and parental views regarding this field were relevant to recruitment. Whilst many parents, particularly those with medical or scientific backgrounds viewed research positively, this was not universally the case. Online discussion forum data reveal that medical research was viewed negatively by some. Snowdon et al. (2007) introduced the notion of 'injurious misconception'. In this concept parents' views of trial participation reflect a dominance of risk, absence of benefits, concern about research in general and the specific characteristics of the individual trial, and a separation of care and research. Data gathered for this study support such a view; those who did not wish to take part saw fewer benefits from participation and viewed the risks of research as greater than those who did enrol their children in the trials. Whilst it would be interesting to understand why these parents displayed injurious misconception whilst others did not, the limitations of the online discussion forum data make it difficult to do so.

The divergence that existed between philosophies of the field of infant feeding and of the trials, in particular of EAT, helps to explain the difficulties with recruitment. Whilst, in the field of infant feeding exclusive breastfeeding to six months of age is deemed important, EAT was trialling the introduction of solid food *alongside* breastfeeding to six months of age. These differing philosophies, particularly when coupled with the substantial symbolic capital that was available to those who practiced or promoted exclusive breastfeeding, had a patent influence on perceptions of equipoise and thus on both parental willingness to accept randomisation and HCP willingness to collaborate with recruitment. That the resources (or capital) that were accessible to those within the field of infant feeding were greater than those accessible to the trial staff helps to explain why EAT staff found it particularly difficult to recruit participants.

Although there was divergence between aspects of the philosophies of those two fields, it is interesting that the fields of infant feeding, parenting, and the trials, shared a collective habitus. Reflecting the emphasis placed on avoiding risk that Beck (1992) considered central to modern society, the habitus of each field reflected a desire to protect children from harm. Parents, trial staff, and HCP collaborators all justified the decisions that they made with reference to the potential for children to be placed at risk of harm. In protecting their children from harm some parents viewed the trials positively. By enrolling their children in the trials and thus interacting with the trial researchers, parents acquired social capital that allowed them to be 'good' parents. The researchers, as HCPs with expertise in the field of paediatric allergy, could provide parents with help that was not available in the field of healthcare and that would result in improvements to their children's health. It was thus evident that personal benefit models of participation had a substantial influence on recruitment.

However, and particularly when parents had no immediate need for the expertise that trial participation could afford, their agreement to take part in the trials also reflected a wish to contribute to society. Whilst other studies have found that parents take part in trials to help others (see for example Pletsch and Stevens 2001b; Chantler et al. 2007; Sammons et al. 2007), the findings of this study suggest that willingness to contribute in this way reflected both their personal characteristics and Titmuss' (1970) notions of social cohesion and understanding of the importance of participation. Parents' choices to enrol their children in the trials were not simply a result of a habitus that predisposed them to help others; it was also a manifestation of their sense of belonging within a specific societal group. In this context this represented membership of a 'food allergic' society

and/or the field of parenting, where members were united by a desire to protect their children from a multitude of risks, of which food allergy was one.

It was also evident that, rather than representing dichotomous motivations for participation, the influence that the potential for societal and personal benefit had on trial recruitment fell along a continuum. For those who felt unable to manage their child's health, personal benefit took priority. However, it is interesting to note that parents who described being motivated by the opportunity for personal benefit seemed to feel guilty about 'using' the trials for personal gain, describing their behaviour as selfish even though any benefits of participation would result in improvements to the health of their children. Although parental discussion of guilt may reflect the social desirability bias that is inherent to interviews, it may also reflect a broader societal view that participation in prosocial healthcare activities should be underpinned by altruism. Regardless of its underpinning, parents clearly considered that societal benefit approaches were preferable and expected or believed that researchers' motives would and should fall within such a model, even if their own did not.

These ideas are discussed further in the following chapter, in which I present the results relating to adherence in LEAP and EAT.

Chapter 7: Agreements and negotiation: adherence in LEAP and EAT

In the context of RCTs, adherence may relate either to the regimen or intervention that participants are asked to follow (in this thesis I shall refer to this as ‘intervention adherence’⁴⁶) or to the additional trial activities (‘follow-up adherence’) such as blood tests or questionnaires that participants are asked to carry out to fulfil the requirements of the protocol (Robiner 2005).

The primary way that parents of children participating in LEAP and EAT were asked to adhere to the protocol was by carrying out their child’s assigned dietary intervention. In LEAP, children were randomised either to consume peanut protein three times a week until the age of five, or to avoid all peanut-containing foods for the same duration. In EAT, children were randomised either to consume cow’s milk, egg, wheat, fish, sesame and peanut twice a week until 12 months of age, with an added request to try to continue this regime until the age of three years, or to avoid those six foods and exclusively breastfeed until six months of age, after when they were free to follow any dietary regime the parents wished.

Parents were asked to complete additional activities alongside adhering to the intervention. In LEAP these included: attending scheduled visits to the clinical trials unit; attending unscheduled visits if parents or staff were concerned that a child had developed peanut allergy;⁴⁷ receiving scheduled telephone calls from staff to discuss their child’s health and diet; completing diaries of their child’s diet; and allowing a trial dietitian to visit them at home or other convenient place to discuss their child’s health and diet

⁴⁶ Intervention adherence refers to adhering to the regime of whichever group children were allocated to. Thus within this term I also include the avoidance of foods that parents of children in the control arm were asked to carry out.

⁴⁷ Staff may have become alerted to potential peanut allergy when taking a medical history during a trial visit or telephone call.

and to observe them eating peanut if they were randomised to the intervention arm. In EAT these included: attending scheduled visits on the clinical trials unit; completing questionnaires about their child's health and diet; and completing diaries regarding their child's diet. If parents or staff were concerned that a child was allergic to one of the six trial foods or if a child had a positive skin prick test to one of the foods, the protocol stated that the child should attend an unscheduled visit at the clinical trials unit to definitively ascertain whether they were tolerant or allergic.

As the trials were ongoing at the time of this study no formal assessment of adherence was available, although EAT were able to provide me with information that over 99% of their participants were broadly adhering to the intervention to which they had been randomly assigned. Given that adherence to medical regimes and research protocols is known to be variable (see for example Bender 2002; Johnson et al. 2009; Thornburg et al. 2010) and is influenced by several factors, including the personal characteristics of the participants (Mihirshahi et al. 2008) and the way that staff view and facilitate adherence (Lawton et al. 2011), I had several questions about adherence in LEAP and EAT that were not answerable with the available literature. How much importance did parents place on fulfilling the activities that the protocol required? How did they come to their decisions about the amount of effort they were prepared to put into adhering? Did they feel able to be honest with the trial staff about their child's adherence? Furthermore, although intervention adherence may offer therapeutic benefit in trials of equivalence, such as when comparing the relative superiority of two commonly used analgesics, in LEAP and EAT, which were both proof of concept trials, it was not known whether intervention adherence would offer therapeutic benefit for the participating children.⁴⁸ Yet not all

⁴⁸ In this instance the 'therapeutic benefit' would manifest as prevention of food allergy.

parents were in equipoise regarding the superiority of the trials' interventions in preventing food allergy, and I wondered whether parents felt that diligent intervention adherence would prevent their children from becoming allergic.

Several authors have highlighted the importance of considering the role of HCPs in adherence, emphasising the need to move away from viewing non-adherence as the sole responsibility of the patient (Fineman 1991; Luftey 2005; Lawton et al. 2011). Therefore I also wanted to explore how LEAP and EAT staff helped the participating families to carry out the trial activities, and whether contextual factors were relevant to trial adherence.

In answering these questions I examine Bourdieu's (1977) assertion that, when individuals come together to work towards a common goal, they create specific rules and contracts to underpin their practices which are based on the valuable resources that each bring to the relationship. These resources, which Bourdieu referred to as capital, allow individuals to advance their position within the field in which they are practising. I contrast this view with that of Titmuss (1970), who considered market like conditions, where participation has personal benefits, to be inadequate. Rather, he viewed feelings of duty and a desire to contribute to society to be a more safe and consistent model to underpin participation in prosocial healthcare activities, although he discussed this with respect to initial participation rather than adherence.

I begin by discussing the emphasis that parents placed on honesty when providing information about adherence to the staff. I then describe how perceptions of adherence were formed even before children were recruited to the trials and how staff and parents' views of a symbolic contract influenced adherence after the children were enrolled on the trials. In discussing the importance that parental perception of benefit and harm had on

adherence, I also explore the discordance between the contract⁴⁹ parents felt that they had with the trial and that which they had with their children, and consider how staff helped parents to resolve this conflict. Finally I describe some of the more practical issues that influenced adherence, including the design of the trials and the constraints on adherence given the dominant practices of infant feeding at the time the trials were being conducted.

7.1 Honesty and accuracy in reporting adherence

Many trials rely on participant self-report of adherence when establishing the efficacy of the intervention. If participants provide inaccurate or misleading information about their adherence then the efficacy of the intervention may be over or under estimated, resulting in inadequate or unsafe interventions being recommended for use in practice (Robiner 2005). In LEAP and EAT, data that were necessary to interpret the effectiveness of the intervention, including information about intervention adherence, were captured through questionnaires that parents completed at regular intervals throughout their child's trial participation. That LEAP and EAT parents provided honest and accurate information about their child's intervention adherence was thus critical for the trials' internal validity.

In my previous role as a research nurse working on LEAP I encountered an occasion when a parent was not honest about his son's adherence. When making one of the scheduled phone calls I spoke to the father of a newly enrolled child who had been randomised to consume peanut. I asked how introducing the peanut snack had been going, and the father said that his son was really enjoying it. When I asked how much he had eaten he said that he was unsure and suggested I call his wife on her mobile. I found the correct number and tried to contact her but the line was engaged. When I phoned back a few

⁴⁹ Throughout the thesis, when I refer to the contract between parents and staff, I use term to reflect a symbolic, rather than an actual, contract.

minutes later I introduced myself and said that I had spoken to her husband and understood that her son was enjoying the peanut snack. She laughed and said that it wasn't true. He hated it and they had been really battling to get him to eat any. She said that her husband hadn't known what to say so had panicked and told me that he loved it. After speaking to me he had immediately contacted her to confess what he had said. Given this conversation, I wondered whether other parents had also found it hard to be honest.

To investigate this question I asked parents whether they had felt able to tell the trial staff the truth about their child's intervention adherence. Most said that they were always honest. This honesty reflected both an understanding that the information they provided would influence the final trial results and their views that the evidence that the trial produced was important. Lily told me that, as she was personally responsible for providing some of the data that would be used in the final results, it was essential that the information she provided was accurate:

So, ok yeah, you're supposed to avoid peanuts, but what if you ate peanuts? Then you really need to cough up because if you don't then whatever results you produce aren't the best results, you know? [...] the research is about the, the things that you put in the research. Because if it's all wrong, like if you say, you know, I love the colour blue, when you really, really love the colour red, then how accurate are the results that come out?

[Lily, L1MC]

The emphasis that parents placed on this honesty also reflected their habitus, the personal values that many articulated that *'if you're going to all the trouble of doing something you may as well do it properly'* [Natasha, E48MC].

I asked parents whether the trial staff had said or done anything to foster their honesty. A couple recalled being told by the staff that, given the age of the children, it was inevitable that some would not adhere and that in such instances parents should not feel afraid to tell the staff. However, predominantly parents had used their previous experiences and knowledge of research to assume that honesty would be important.

Titmuss (1970) discussed the importance of blood donor honesty in ensuring the safety of the donated blood for the recipient. He compared the differences in rates of hepatitis in recipients of donated blood in the UK and USA taking account of the way in which the donor programmes were organised. He suggested that donors who were motivated by altruism (UK donors) were more likely to be truthful than those motivated by personal, in this case, financial, reward (USA donors). He therefore concluded that participation in activities that were designed to help others was safer when underpinned by a hope for societal benefit than when underpinned by a hope for personal benefit.

As I argued in the previous chapter, parent's primary motivation for participating in LEAP and EAT reflected either the societal benefit or personal benefit models. I wondered whether the data gathered for this study contained evidence of Titmuss' (1970) assertion that those who take part for personal benefit are likely to be less honest. When analysing the data I explored whether a relationship existed between LEAP and EAT parents' original motivation for participation and their willingness to be honest with the staff about their child's adherence.

Within the data that I gathered, the emphasis that parents placed on being honest bore no relation to their original motivations for participation. I asked parents directly whether, on occasions when they had not adhered to the protocol, they had been tempted not to tell the truth, and all except one parent said that they had been honest,

even if this meant admitting non-adherence. As Lizzie, who took part because she considered the trial to be answering an important question explained:

Ultimately it doesn't help anyone if it's sort of skimmed over. It needs to be as it is. The research is relying on it, there's no point in just fudging over. [Lizzie, L20MI]

Ada was the only parent who said that she had not been honest with the trial staff. At the beginning of the interview she told me that she took part in LEAP 'to help' [others]. Her son was randomised to the control arm, and she explained that, as peanuts were a large part of the diet of her culture and thus were frequently available when visiting family and friends, avoiding peanut required constant vigilance. She described how, on one occasion, she realised her son had a peanut in his mouth which she had immediately removed. When I asked whether she had told the staff about this she looked guilty and said:

Ada: I just thought it was negligible because it would be very little, like there [motioning to her mouth] and put it out, so.

HF: Oh ok, so he put it in his mouth and you took it out?

Ada: Yeah something like that, but I'm not, can't be 100% sure if he did take any one behind me.

HF: Yeah, I know, it's difficult. Um, if you realised that he had definitely eaten some peanut do you think you would feel able to tell the study staff?

Ada: I think so, if it was, cos he wouldn't have done it in front of me, so I wouldn't know, but if I think he's had quite a substantial amount that would affect it, then I think I would be bound to tell them. If not it would affect the results of the study, and the research, yes. [Ada, L22MC]

Thus Titmuss' (1970) assertion that individuals who personally benefit from their participation in prosocial healthcare activities will be less inclined to be honest was not reflected in the data gathered for this study. The only parent who had not been honest gave an altruistic motivation for participation and, regardless of their reason for taking part and whether or not they had been honest, parents recognised the need for truthfulness. Of course parents may not have told *me* the truth about whether they were honest with trial staff; admitting that they had lied about their child's adherence would not have been an easy thing to do. However, from the frequency of the answers that were given and the way in which parents discussed their understanding of the importance of honesty, their answers appeared genuine. Furthermore the staff felt that, given the number of parents who admitted non-adherence, it was likely that most told the truth.

Although parents' truthfulness about their child's intervention adherence is likely to have had a positive influence on the validity of the trials' data, the importance that they placed on providing honest and accurate data actually had a negative effect on follow-up adherence, specifically on their completion of the questionnaires. This reflected parents' perceptions of the rigorous nature of practices within the field of medical research. Mercy told me that she had not always completed the three-day food diaries for LEAP on time. She explained that her daughter often went to play at friends' houses and so she preferred to delay completing the diaries until they were both at home together for three days. She said that she did not want to question her friends about whether her daughter had eaten anything whilst visiting them, but equally she did not want '*to lie on paper*' [Mercy, L7MC]. For Vicky, whose daughter participated in EAT, an inability to accurately recall what her daughter had eaten meant that she:

started getting a bit behind on filling in the forms as well [...] I think mainly just because you were busy, and you'd think, I'll do it later and then you'd realise that you couldn't quite remember, so you weren't quite sure whether you were filling it in accurately or not.

[Vicky, E51MIW]

She went on to explain that she considered the diaries to be pointless if the data she recorded were not completely accurate. If she could not complete them accurately, she chose not to complete them at all.

Although most parents did not recall the trial staff explaining the importance of honesty when reporting their child's adherence, the expectation of adherence itself was made more explicit. As I describe in the following section, thoughts about adherence began even before children were recruited to the trials.

7.2 Setting out the contract: adherence begins prior to recruitment

Both staff and parents thought about adherence to the protocol even before children were enrolled on the trials. The information sheets provided to parents considering participation in LEAP or EAT included a short paragraph on 'parent responsibility' which informed parents that *'The greatest responsibility is to carry out the required study intervention'*. The staff also spent considerable time explaining the trial to parents, in particular emphasising its randomised nature and confirming that parents were happy to accept either group. Thus their expectation of intervention adherence was made explicit prior to enrolment. This appears to have had a positive influence on intervention adherence. As Cara explained, the majority of EAT parents fulfilled the requirements of their child's allocated group:

HF: Just roughly, what kind of proportion of your parents are doing what they're asked to?

Cara: I just did a compliance report yesterday so I can tell you. An alarming amount! [Out of approximately 350 children randomised to intervention at the time of the interview] there were only three children by six months who hadn't introduced any of the six foods. [Cara, Staff 07]

The information sheet and the approach of staff to ensuring that parents were willing to accept randomisation made their expectations for families trial participation clear. In doing so the staff could be considered to have invited parents to accept or decline a symbolic contract of participation. The notion of a contract, or mutually agreed plan of action (Bosch-Capblanch et al. 2007), has been discussed in relation to adherence by a variety of authors (see for example Fineman 1991; Burkhart et al. 2002; Dean et al. 2010). Fineman (1991) explored adherence to health and social care regimes by the users of a downtown American healthcare and social service agency. He argued that the staff viewed patient adherence in terms of their fulfilment of an informal contract, and that poor adherence represented the breaking of this contract. He also reported that, although the staff viewed patients' adherence in terms of a contract, they felt that the patients did not hold the same views. Patients did not consider that the help they received from the staff was reliant upon their willingness to carry out the activities they were asked to (Fineman 1991).

Contrary to Fineman's (1991) findings, LEAP and EAT parents did seem to view their participation, and thus their willingness to adhere to trial activities, in terms of the acceptance of a contract. This was apparent in the considerable thought that they gave to whether they would be able to adhere to the requirements of the protocol before they

decided whether or not to take part. Parents who had concerns about whether they would be able fulfil these requirements delayed agreeing to participate until they thought they could manage the activities that would be expected of them. As I recorded in my field notes of my observations of pre-enrolment conversations, parents also often initiated discussions with staff about adherence, seeking clarification about what might happen if they were unable to adhere:

A mother asked Katerina what would happen if she couldn't get to six months without weaning and Katerina said that was a good question that lots of parents asked. She said they didn't want to cause the child or parent any distress and if the mum felt that she really wanted to wean then there were ways of doing this and that she should call the study at that time and they could talk about it.

[Field notes, 17th February 2011]

As this excerpt also illustrates, staff seemed to welcome these pre-enrolment conversations about adherence and provided reassurance that they would try to support parents to adhere as best as they could. Yet, although the staff sought to reassure parents who were concerned about adhering prior to enrolment, they tailored this to the individual circumstances of the families. This sometimes meant discussing with the parents whether adherence and, therefore, participation would be realistic. Douglas gave an example of a mother who had various food allergies, was exquisitely sensitive to peanut, and did not feel comfortable having peanut products in her home. She was keen to enrol her daughter in EAT, but both she and the trial staff were concerned that, if the child was randomised to the intervention arm, she would not manage to give her daughter the peanut in the quantities and frequencies the protocol required. The mother was exploring whether family or friends might be able to give her daughter peanut on the two occasions a week that the trial protocol required, but as Douglas explained:

It depends quite a lot on the support mum has to do it, because really you have to, it has to work in context and it has to work practically [...] we, and the study, talk very much about how to make it manageable for the ways in which you give the specific foods. But that's within the context of you managing it regularly, not only for weeks, not only up to six months, but actually we really want you to continue doing it longer, as a, as a way of life. [Douglas, Staff 06]

Following such discussions parents who were unlikely to be able to adhere either chose not to take part or were advised by trial staff that participation would not be manageable for them. As I will show in the following section, these pre-enrolment conversations, and parents' past experiences and personal values were relevant to adherence once the children had been enrolled on the trials.

7.3 Fulfilling the contract: parent approaches to adherence

The approaches that parents took to intervention and follow up adherence reflected the importance that they placed on carrying out these activities and the effort they were willing and able to expend in this regard.

7.3.1 *Parental views of the importance of adherence*

During the interviews I asked parents how they had found participation, in particular carrying out the activities that they had been asked to do. Their responses indicated that they attached considerable importance to conducting the trial activities to the best of their ability. I wondered whether the emphasis that they placed on intervention adherence reflected their belief in the trials' hypotheses, and whether they thought that diligent adherence would protect their child from developing food allergy, i.e. that adherence would have a 'therapeutic' benefit for their children.

Although some parents felt that following the regime might help to prevent their children developing food allergy, for the most part this was not the case and did not seem to reflect the diligence that many applied to adherence. Rather, the effort that parents put into completing the trial activities reflected their belief that their conscientious participation would contribute to the trials' goals. Lorna, who enrolled her son in EAT because she wanted to help advance knowledge about food allergy, told me that, having agreed to participate, she felt that she now had a duty to carry out the activities she had been asked to:

They give you a required amount to eat. If he's not eating all of that then we haven't done as much as we should do [Lorna, E47MI]

This view, and thus the emphasis that parents placed on adherence, reflected Titmuss' (1970) view of social responsibility as an underpinning for prosocial healthcare activities. Parents felt that their adherence would help to ensure that the findings of the trial were accurate, and thus that the results would make a meaningful contribution to learning more about the causes and prevention of food allergy. This view was also reflected in the effort that parents expended on facilitating their child's adherence.

7.3.2 The effort of adherence

The effort that parents needed to expend on adherence varied. Some parents, particularly those whose children had been randomised to the control arms of LEAP and EAT, described finding intervention adherence relatively unproblematic because they would probably have avoided the foods even if their children were not participating in research. Parents whose children had been randomised to the early introduction (intervention) arms generally talked more about difficulties with adherence. Yet, although parents reported that adherence was not always easy, the importance that they placed

on carrying out the activities they had been asked to meant that they spent significant time and effort in finding ways to get their child to consume the foods. This included cajoling, disguising the foods and thinking up novel recipes to try to improve their child's adherence. Janet was one of several parents who established routines:

I think I've instilled habit now, so whenever we go swimming, cos she's hungry after swimming, she always asks for Bamba [the peanut snack given to LEAP children]. I always happen to have one in my bag, so that's one packet done, tick. [Janet, L6MI]

Parental willingness or ability to expend the effort that was required for intervention and follow up adherence was variable. Parents' life circumstances sometimes meant that adhering to the trial activities would wane, often just for a short period of time until the situation resolved or they adjusted to their new circumstances. Various life events reduced parental ability to adhere to the protocol, including a return to work after maternity leave, the need to care for sick relatives or changes in family circumstances. A commonly cited explanation for problems with adherence was the birth of a new baby, and Mark told me how his family's adherence waned at this time:

The study have been great in sending forward recipes and ideas, but when [my son] was two we had twins and so a lot of planning and a lot of organisation went out of the window as two zombies tried to look after three children. [Mark, L16FI]

Several studies have highlighted that adherence to medical regimes and trial interventions tends to lessen over time (Martin et al. 2000; Johnson et al. 2009; Thornburg et al. 2010), and data from this study seem to corroborate this finding. Parents whose children were participating in EAT and thus who had recently begun participating in the trial seemed to adopt a stringent approach to adherence. During the interviews

EAT parents commonly described trying really hard to adhere and some felt considerable pressure to ensure that their children ate every food in the correct quantities. In response to a question about how introducing the foods was going, Nadia, whose daughter was randomised to the intervention arm of EAT, told me:

Nadia: Um, that one's been more, more tricky I guess, there's more pressure to make sure that she eats it, so there's been more of a 'come on, you will eat it'.

HF: And when you say a pressure was that kind of an internal pressure or?

Nadia: Yeah for me, no, from me, because I'm sort of a stubborn person and I think, right, come on, this is where we've got to head towards. [Nadia, E45MI]

LEAP parents, whose children were older and had been enrolled in the trial for at least a year appeared more philosophical about adherence. Whilst they thought it was important to adhere and tried their best to make sure their children ate the correct amount of peanut or avoided peanut containing foods, they had come to recognise that intervention adherence was not always possible. LEAP parents also talked more about being too busy to devote substantial time to adherence. Jemima explained that *'it's either got to be easily administered or it's just not going to work'* [Jemima L2MI]. The approach taken by LEAP parents may also reflect the fact that, at the time of the interviews, many had returned to work or had younger children whilst the majority of the EAT mothers were first time mothers and were still on maternity leave.

Reflecting the habitus of the parenting field, parents also discussed their non-adherence in terms of doing their best for their children. Whilst this was evident in the interviews of

both LEAP and EAT parents, it was more commonly discussed by LEAP parents, perhaps because they had been participating for a longer time or because they had greater parenting experience. Xanthe explained that her son would not always eat the peanut when she wanted him to but that she chose not to take too strict an approach as she considered this may be detrimental both to his future adherence and to his perception of food and meal times; her parenting experience had taught her that it was impossible to force a toddler to eat something they did not want.

I explore this further in the following section, in which I discuss the conflict that parents sometimes felt between fulfilling their contract to the trial, and fulfilling their contract to their children.

7.4 Balancing parental responsibilities and the trial contract

In the previous sections I described how parents understood that their adherence would influence the results of the trial and, facilitated by the approach staff took prior to their enrolment, devoted considerable effort to adherence so that their contribution allowed the trials' results to be meaningful. I also described how life circumstances influenced the extent to which parents were able to adhere. Parental perceptions of whether carrying out the trial activities was harmful or beneficial to their child were also relevant to adherence.

7.4.1 Harm

In Chapter 6 I argued that recruitment to LEAP and EAT was influenced by parental perceptions of the need to contribute to society and of the need to be a good parent. Earlier in this chapter I described how adherence was enhanced by the emphasis that parents placed on contributing to society, and the contract they perceived they had entered into when they agreed to participate in the trial. The data suggest that the

responsibility that they felt to their children was also relevant. As I will go on to describe, when fulfilling their duty to society and protecting their children from harm were both possible then parents were happy to adhere. However, despite the importance they placed on carrying out the activities they had been asked to, if parents felt that adherence was harmful to their children, their views, and thus their behaviour, changed.

During the interviews I asked the staff about the reasons that parents gave for non-adherence. They told me that intervention adherence was often influenced by parental perceptions of harm. Michelle gave an example of a family whose child had been randomised to the control arm of LEAP but who, after a few months of participation, decided to give their child peanut, i.e. to swap randomisation arms. She explained that their motivation for this reflected a lack of equipoise and a worry that adhering to their allocated group may cause their son to become peanut allergic:

They think they're doing the wrong thing, so they, they want to feed their child [peanut]. I think they, they've been doing a lot of reading [...] they feel that to do the best thing for their child they should give them peanut.

[Michelle, Staff 12]

Concerns about whether adhering was harmful to the children were also expressed by parents themselves. Lyndsey was one of many parents who said that there were times when her son refused to eat the foods that the protocol required and, although she considered their non-adherence regrettable, in such situations she did not want to force feed her son, as this may be harmful:

So I'm not that worried about it [if her son won't eat the required portion size]. I know that doesn't help the study but at the end of the day he's, he's, I don't want to force something down him that, that then might form a phobia for life.

[Lyndsey, E39MI]

Parental desire to protect their children from harm also had a detrimental effect on follow-up adherence. Parents who chose not to attend the scheduled visits or refused to allow their children to have a blood test cited concerns about harm. Penny explained that this was especially true of children with other health conditions who had to attend medical appointments that were unrelated to the trial. She gave an example of a family who did not attend one of the scheduled visits because:

they felt it's too much, and for example with the, this child, there's so much going on, you know she's got a [chronic health condition] and she's going for an operation and other things, so mum thought it a bit much for her to come to the visit.

[Penny, Staff 08]

By citing concerns about harm and the need to do their best for their children, parents' explanations for non-adherence reflect the 'rules of the field' (Bourdieu 1992), of one of the fields within which they were practicing. As the underpinning philosophy of the parenting field is the protection of children, it is easy to see why concerns about harm would result in parents choosing not to adhere.

Not all parents found it so easy to balance their parental responsibility with their perceived need to adhere to the trial's activities. Isla told me that she had tried hard to get her daughter to eat the foods that were required, persisting even though her daughter would vomit and become distressed. She described persevering because she wanted the contribution she was making to advancing knowledge about food allergy to be worthwhile, but over time she felt increasingly uneasy about persisting when her daughter was clearly suffering. After some time realised that it was not possible to fulfil both her duty to protect her daughter from harm and her duty to adhere to the trials' activities. As her priority was to protect her daughter she felt that adhering to the intervention was impossible.

Although parents said that concern that conducting the trial activities was harmful to their child led them not to adhere, as I explore in the following section, adherence appeared to be improved if parents thought that carrying out the trial activities would benefit their children.

7.4.2 Benefit

Earlier in this chapter I described how parents put substantial time and energy into adhering because they felt that to do so was important for the trials' final outcomes and thus for advancing the scientific community's knowledge of food allergy. Stemming from their perceptions that the trial would provide important information, this approach to adherence reflected Titmuss' (1970) view that participation in prosocial healthcare activities stems from an understanding of the importance of the activity for society.

Although Titmuss (1970) considered personal benefit to be an inadequate model of participation, it is evident that, in the context of LEAP and EAT, this approach positively influenced adherence. Several staff thought that, although most parents tried hard to adhere to the protocol, those who felt that they would not gain useful information about their child's health were slightly less likely to attend the scheduled and unscheduled visits than those for whom the information was beneficial. Tess told me that parents whose children were in the intervention arm seemed less willing to attend an 'unscheduled' food challenge visit than parents whose children were in the control arm of EAT. She hypothesised that this difference was due to the beneficial knowledge that attendance could afford:

The majority of mummies [whose children] have come up positive [on skin testing] in the control arm are quite happy to come back [for a food challenge to ascertain definitively whether their child is allergic]. And it's actually because the control arm, you know the ones who have [had a]

positive [skin test] have actually probably not been eating, or not been eating a lot of [a particular food]. So they've been the egg ones who have had an odd cake or biscuit with egg in but not sat down and eaten a whole scrambled egg,⁵⁰ and to them they're learning something [whether their child is allergic or not]. They're gaining some information. So yeah, as far as I'm aware no control mummies are refusing to come back for a challenge, they're all quite happy to come back. But then I don't know, my feeling is that's because they feel that they're getting something out of it, and I suppose to an eating mummy, who's [child is] eating [egg] regularly [and is therefore not allergic despite having a skin test that indicates that they might be], they're not going to gain anything from [attending the food challenge visit], so what's the point in coming on a train all the way to London for a whole day. [Tess, Staff 19]

This finding builds on the view, discussed in the previous chapter, that trial participation allowed parents to acquire social capital by promoting access to expertise that was valuable for fulfilling their parenting role, particularly given the concerns about food allergy that were evident within society. It also highlights that, contrary to Titmuss' (1970) findings, there are instances in which personal benefit models of participation in prosocial healthcare activities are superior to societal benefit models. This seemed to be particularly true when parents were asked to complete 'additional' activities to those that they had assumed would be necessary when they agreed to take part in the trial. For example, although the parent information sheet mentioned that unscheduled visits would be conducted if children showed signs of allergy, the trial staff did not believe that many children would require one of these visits and it is likely that parents similarly considered that they would probably not need to attend such a visit. When it became apparent that they would need to do so the burden of their participation increased.

⁵⁰ This means that parents and staff cannot be certain that the child is not allergic because some allergic children can tolerate small amounts of well cooked egg (as in a cake) but not less well cooked egg (as in scrambled egg).

Rather than needing to attend three visits at roughly yearly intervals, they were asked to attend four (or even more) visits, some of which would be within relatively short periods of time. It is possible to see why, in such circumstances, the personal benefit model of participation had a more positive influence on adherence than the societal benefit model. I will discuss this notion further in Chapter 8, when I consider trial retention.

So far in this chapter I have predominantly explored the approach that parents took to adherence. However, as I discuss in the following section, the trial staff also had an important role to play.

7.5 Staff approaches to adherence

Staff working on LEAP and EAT considered parents' adherence was critical to the trials' success. The importance that they placed on adherence was illustrated when both I and another PhD student asked for permission to invite LEAP and EAT families to take part in our studies. Due to concerns that these projects might detract parents' attention from participation in the main trials, the requests were given extensive consideration and were only approved when the funders and members of the trial steering committees felt reassured that this was unlikely to be a significant threat to ongoing trial success.

LEAP and EAT staff devoted considerable time to helping parents carry out the trials' activities. Some of the activities, for example explaining to parents what they needed to do to adhere, had been thought about before the trials started and thus the time and resources that were required had been allocated in the trials' initial budgets. However, it was evident from my observations that a substantial amount of the work of facilitating adherence was unplanned and involved staff responding to occasions where parents were not managing to adhere or where they were finding adherence to be very hard work. Although neither trial had budgeted specific resources to attend to these

impromptu requirements, high priority was given to parents who requested or were identified as needing help. For example Rachael told me about a family she had helped to attend one of the scheduled visits. Whilst most families organised their own transport to the clinical trials unit and were reimbursed for their travel costs after they had been incurred, on this occasion this was not feasible. To ensure that the family were able to attend the visit, Rachael rescheduled her working day to organise the transport and accommodation that the family needed:

One of the parents who were travelling from [abroad] was, in terms of finance, er a little bit more complicated because we had to, er pay for their flight and their accommodation etcetera, and arrange all of that [...] and that had to be done, you know, they had received their visa one day, and they were able to come virtually the next day, so it had to be done there and then.

[Rachael, Staff 09]

The effort that the trial staff put into assisting parents to adhere depended on a variety of factors. Fineman (1991) found that, in his study, staff categorised patients in one of two ways: either as unwilling to adhere or as unable. He believed this distinction to be important because, within the data he gathered, patients who the staff deemed to be unwilling to adhere were subjected to sanctions, whilst staff invested additional effort and resources into assisting those that they judged to be unable to adhere.

Although LEAP and EAT staff talked about a few parents in terms that suggested that they felt they were 'unwilling' to adhere to the protocol, they generally discussed non-adherence in terms of parental inability to conduct the activities that were required. Staff seemed to feel a real empathy for parents, as this quote from Cara illustrates:

People try really hard and it's really touching, it's lovely that they put so much effort in and um, I find that hard. And when they struggle I want to

say 'oh just stop, don't do it, cos it sounds hard'. But no, you just have to support them and try to get them through that. [Cara, Staff 07]

As Fineman (1991) suggested, constructing non-adherence in this way perhaps gave staff reason to invest additional time and resources to helping families to carry out the trial activities. However, their willingness to expend so much effort facilitating families' adherence is also likely to reflect the fact that achieving good levels of adherence was essential to the trials' final outcomes.

In the previous chapter I described how the expertise the trial staff possessed meant that trial participation allowed parents to accrue social capital. In the context of adherence, parents' participation was also a source of social capital for the trial staff. By facilitating their child's adherence parents provided the trial staff with an important resource; the data from which the results that were needed to help to advance knowledge would be derived. Furthermore, if the trial findings made a meaningful contribution to knowledge then the careers of the staff, particularly the senior staff, would be enhanced. This is likely to have provided an additional impetus for staff to devote time and resources to facilitating adherence.

The staff employed a variety of strategies to facilitate adherence. In her study of ways that staff help patients with diabetes to adhere to therapeutic regimes Luftey (2005) considered that HCPs drew upon the skills that were used in various common social roles: those of educators, detectives, negotiators, salesmen, cheerleaders and policemen. Four of these were evident in the repertoire of roles that LEAP and EAT staff adopted when facilitating adherence: educators, detectives, cheerleaders and negotiators. In the following sections I discuss how staff came to adopt these roles, the instances in which they were used, and parents' views of the differing roles.

7.5.1 *Educators*

A key way that staff promoted adherence was by ensuring that parents understood the activities that they needed to conduct when they were taking part. After randomisation staff spent considerable time educating parents about the activities that were relevant to their child's randomisation group. I observed EAT staff during these activities and they seemed to allocate as much time as the parents needed, answering all their questions.

Both LEAP and EAT staff provided written information to complement the verbal information and EAT staff also developed a video that parents could access from home that contained key information about intervention and follow up adherence. Staff also produced other written resources to assist with adherence including diary sheets to help parents keep a record of the foods their child had consumed and recipe booklets to aid intervention adherence. These resources were updated during the course of the longitudinal trials; follow on recipes booklets were provided at later time points in the trial to promote continued adherence as children grew up and their tastes changed.

Many parents commented on the thoroughness of these initial conversations and documents which, Hazel explained, helped her to understand what she should do to adhere:

So they explained very well what was very important to avoid and what actually might have peanut oils in it but wasn't bad. [Hazel, L5MC]

In addition to teaching parents about how they should adhere, staff also used education to explain why they should adhere. This approach was evident in the response that the LEAP investigators adopted to the publication of the findings of an observational study (Du Toit et al. 2008) that they thought would receive wide media attention. The results of the observational study indicated that the LEAP hypothesis, that early consumption of

peanut is more effective at preventing peanut allergy than avoidance, was correct. Due to concerns that parents in the avoidance arm of the trial may decide to give their children peanut products, LEAP investigators attempted to pre-empt non-adherence by writing to parents. Reflecting their educator role and the priority that staff gave to high quality scientific evidence that I discussed in Chapter 7, the letter explained the differences between RCTs and observational studies. It also highlighted that LEAP was investigating the issue in a more scientifically robust manner than the observational study that was being published, and thus that both groups' continued adherence was important for the successful completion of the trial:

[The beginning of the letter briefly described the observational study's findings] ...what exactly does this study mean? First, and most importantly it does NOT, in any way mean that eating peanut early in childhood will prevent peanut allergy [...] there may also have been other unmeasured or unknown 'confounding' factors which could have influenced the results [...] the LEAP study, using a strong, randomized, controlled design, stands the best chance of answering the question about how to prevent peanut allergy.

[Leap letter to parents about observational study]

By educating parents in these ways LEAP and EAT staff took a proactive approach to facilitating adherence. The staff also used a proactively reactive approach by becoming 'detectives'.

7.5.2 *Detectives*

Data from the observations and interviews reveal that staff tried to be alert to occasions where parents were not adhering to the intervention. Whilst parents often told staff of their non-adherence, on other occasions detective work was required.

The trials' designs influenced the degree of detective work that staff needed to carry out. During the planning phase of LEAP some members of the protocol development team were concerned about the safety of giving infants peanut protein. To address these concerns the LEAP protocol required that staff phone parents on a regular basis to ensure that children were not suffering adverse effects from consuming peanut. To ensure equivalence between the groups, the parents of children randomised to the control arm also received phone calls. These calls also provided an opportunity to gather data about the child's avoidance or consumption of peanut, and I recorded in my field notes how these discussions allowed staff to identify parents who were finding adherence difficult and to offer them support to overcome these difficulties:

During a telephone call between Penny and a parent the parent said that her child had gone off peanut and she was just about managing to get her to eat one packet of the peanut snack and one slice of peanut butter a week [I obtained the mother's side of the conversation from Penny after the call had finished]. Penny said that she could send her the recipe for peanut cookies 'if she thought she would have time to make them'. She checked that she had the correct email address and then said that she would email the recipe through today.

[Field notes, 14th July 2010]

For LEAP staff, therefore, providing that parents were contactable, a subject that I will discuss in greater detail in the following chapter, then limited detective work was necessary; it was usually fairly obvious if parents were having problems with adherence.

The role of detective was more necessary for EAT staff. Due to the number of participants and the level of funding, there was no planned telephone contact with parents. Data were gathered via online or postal questionnaires, although an 'open contact' policy was

operated; parents were invited both verbally by staff at the visits, and through phrases in all trial documentation, to contact the team at anytime if they had queries or concerns:

Questions? Need Advice? Contact the EAT study team at [free phone
telephone number or email address] [EAT best for baby booklet]

Despite these invitations parents did not always contact the trial staff if they were finding adherence difficult. Parents told me that they felt reluctant to contact staff when they had problems with adherence or were unsure how to complete documentation. This reluctance reflected both the fact that they were busy and a concern that admitting they were not able to adhere would make them appear to be 'bad parents'. These views appear to be a manifestation of their parenting habitus, that they must do their best by their children. First time mothers particularly expressed concern that as the intervention involved feeding their children, an activity that they would complete regardless of their participation in the trial, they felt that they ought to be able to manage. These concerns were perhaps also the result of their new membership to the parenting field; they were still trying to establish their position in a field in which considerable intervention and monitoring occurs (Gillies 2012) and where prestige, or in Bourdieu's (1986) terms, symbolic capital is accrued when others within the field deem parents' to have satisfactory child rearing skills.

Parental concerns about appearing to be bad parents were unfounded. EAT staff recognised that there would be times where the children would not eat the foods in the quantities or frequencies that were required and had various strategies to assist with this. However, as they did not have the same degree of personal contact with parents as LEAP staff, their ability to identify these sorts of problems was reduced. It was in these instances that detective work was useful.

EAT collected data via online questionnaires, and the staff had set up the electronic system in such a way that, if the responses to the questionnaires indicated reduced intervention adherence, then the investigators received an electronic alert. These alerts allowed the staff to contact the parents and offer advice or support that could improve adherence. However, if parents did not complete the questionnaires at all then the staff received no such alert. This oversight meant that, for some time, staff were unaware when parents were not completing the questionnaires. Realising this mistake they implemented a system where they checked whether parents were completing questionnaires or not. Several of the staff members told me that as they began to contact parents who had not completed their questionnaires, they came to realise that non-completion was often also an indication of problems with intervention adherence. As Douglas explained:

[the questionnaires are] a really important way of checking involvement,
and it's a good indirect check on compliance [Douglas, Staff 06]

Following this realisation EAT staff allocated protected time to 'detective' activities. Each week one of the staff members identified and tried to contact parents who had not completed two consecutive questionnaires. This facilitated discussion about any problems the parents were having with participation and the staff felt this approach had a positive effect on adherence. Cara told me that:

We get to them before they've completely fallen off the wagon if you
like [...] so we're not waiting til six months down the line and they turn
to us and say, 'well I didn't do anything'. [Cara, Staff 07]

If detective work identified problems with adherence, a third role, cheerleading, was often employed.

7.5.3 Cheerleaders

When I asked staff about the ways in which they helped parents to adhere to the intervention, many discussed the importance of supporting and encouraging the parents. During my observations I noted that staff often praised the parents for the effort they had taken to adhere, but interview data suggest that the cheerleading role was most utilised when parents had problems with adherence.

The need for and use of the cheerleading role reflected both the effort the parents put into adherence and the understanding possessed by LEAP and EAT staff of this effort. As Katerina explained to me:

[If parents do not adhere they feel] pressure from the point of view of um, not meeting our expectations and they all come back and say I've, I've failed you, you know [my child's] not, not meeting the guideline weekly amounts. But then you kind of have to go back and reassure them [...] so I think the main kind of point that we always try and get across is to just make them feel better, make them feel more relaxed about the situation.

[Katerina, Staff 15]

The staff told me that the pressure parents felt to adhere meant that facilitating adherence often required them to encourage and reassure parents that they were doing well, even if they were not managing to fully adhere. They felt that this was important to parents continuing to facilitate their children's participation in the trials, a point I will explore further in the following chapter. However, data from one of the interviews suggests that this approach also had a negative influence on adherence. Brigitte told me that she was confused because the LEAP staff *'asked me to give [my daughter] the full amount [of peanut], and if I gave her only one spoon they were happy and they said that's enough'* [Brigitte, L28MIW]. She went on to say that because of this she continued to give her only as much peanut as she wanted; she stopped worrying about trying to give as

much as she had been asked to. Thus Brigitte took the staff's reassurances to mean that giving the required amount of peanut three times a week was not important. In her case at least, this approach meant that intervention adherence was reduced.

The cheerleading role was not generally used in isolation. The staff provided support and reassurance to parents but also negotiated adherence with them.

7.5.4 *Negotiators*

LEAP and EAT staff considered it important that parents adhered to the protocols and developed systems to try and detect problems with adherence at early stage, but they also accepted that not all parents and children would adhere all of the time. Staff considered that how well parents were able to manage the interventions was important information for the final results and recommendations, and frequently used terms such as '*pragmatic*' [Ed, Staff 04] or '*real life*' [Hugh, Staff 03] to refer to the trials.

Although their 'behind the scenes' position was that the trials were pragmatic, Anton explained that, when discussing adherence with parents at the beginning of their participation, they needed to adopt a more stringent approach:

The trouble is, once you, if you, from the start, say, 'well it doesn't really matter what you're doing as long as you're sort of roughly within what we're saying' then, um, it's very likely that parents, people, will go off at tangents and start doing their own thing from day one. And then you are going to, um, potentially er, um, compromise the scientific value of the study, and that would be unethical. [Anton, Staff 10]

Whilst staff presented a rigorous approach to adherence at the beginning of a child's participation, this was re-examined if parents struggled to adhere. Sometimes the strategies the staff used to promote adherence were inappropriate or ineffective, for example if parents' life circumstances were overwhelming or, despite their best efforts,

children refused to eat the foods they were asked to. It was in these situations that the role of negotiator was necessary. Adoption of this role involved a dialogue between staff and parents to agree a level of participation that was as close to the protocol as possible, but that was manageable for participating families. These negotiations were often staged, with staff and parents agreeing to one course of action but reviewing the approach after a period of time and, if necessary, renegotiating. Adele explained that this could involve 'giving permission' for the parent not to adhere to aspects of the protocol:

Well at some point you've got to say 'well the best that you can do is what we'll accept', because otherwise, you know, it's just very demotivating.

[Adele, Staff 11]

Whilst LEAP and EAT staff were willing to negotiate adherence with parents, parents themselves were often unaware that this was an option. Their perceptions of the field of medical research and thus their view of the contract they had entered into was a stringent one and they considered that they must complete the activities that were required to ensure that the data would be meaningful. However, in these trials, the 'rules of the field' (Bourdieu 1992) had been modified, and parents were surprised, but relieved, to find that reduced adherence was acceptable.

The staff not only negotiated adherence with parents, they also negotiated amongst their own team members. Whilst all staff wanted to encourage adherence, they had differing thresholds for the level of adherence that they thought was achievable. These thresholds seemed to reflect the seniority of the trial staff and the degree of contact they had with the participating families. More senior and experienced staff, who often had less contact with the families, seemed to take a more stringent approach to promoting adherence. This finding perhaps reflects the influence that the trials' findings would have on their

future career prospects. They recognised that poor adherence might result in an inability to detect which of the interventions was effective and thus would limit impact of the findings. As Anton's earlier quote highlights, they also wanted the trials' findings to be meaningful so that the participants had not been exposed to unnecessary procedures and the resources invested in the trial were not wasted.

The differing thresholds for encouraging adherence also reflected the extent to which staff perceived the trials to be pragmatic. Ed described a discussion that the trial team had about whether an alert message should be shown to parents completing online questionnaires if they reported that their child had consumed less than 50% of the required amount of foods. Some staff felt that '*the proof was in the pudding*' [Ed, Staff 04], and the alert was unnecessary; if children were not consuming the correct quantities, then this spoke to the manageability of the intervention and its utility for everyday practice. Others considered it was important to find out whether, under ideal trial conditions, the intervention was effective and thus felt that they should strongly encourage intervention adherence. This highlights the differences that can exist, even within small teams, regarding views of the pragmatic nature of a trial and thus to the approaches that should be taken to promoting adherence.

Thus the approach that staff took to promoting adherence reflected their belief in the value of adherence for the trials' outcomes and, perhaps, for their career progression. It also depended on the resources that the staff could draw upon and their perceptions of the pragmatic nature of the trials. Whilst adherence was influenced by the parental and staff approaches to conducting the trials activities, as for recruitment, more practical aspects were also important.

7.6 The practicalities of adherence

Earlier in this chapter I discussed how adherence was influenced by the approaches that parents and staff took to adherence and their views of the potential for children to derive benefit or experience harm. Whilst these factors were clearly important for adherence, as I describe in the following sections, more practical issues were also relevant.

7.6.1 *Trial design*

The designs of LEAP and EAT had both a positive and negative influence on adherence.

Both trials attempted to develop protocols that minimised burden, restricting the visits to a number that was considered feasible. LEAP staff even conducted two of the seven scheduled visits in parents' homes (or other convenient place) to minimise the number of occasions they were asked to travel to London with their young children. Parents often commented that they found conducting the trial activities easy, and this is likely to have had a positive influence on adherence.

Although the investigators' intention was to design protocols that minimised burden and thus promoted adherence, they needed to balance this with obtaining scientifically robust data. Given the novel nature of the RCTs this was not always easy to achieve. Knowledge of the process through which infants became allergic or acquired tolerance to foods was limited at the time that LEAP and EAT were being conducted. During protocol design the trial investigators anticipated, using previous clinical experience, that almost all children who were regularly eating the 'trial foods' with no obvious allergic reactions would have negative skin tests. However, once EAT children began attending their first follow up visit a good number were found to have positive skin tests despite their parents describing that they regularly consumed the foods at home without any problems. Essentially their skin tests were falsely positive and although neither the parents nor staff were concerned

the child was allergic, the protocol required that they attend the clinical trials unit for an unscheduled visit to establish this using the gold standard tool of an oral food challenge as this would achieve the most scientifically robust trial outcomes.⁵¹ Although some parents did agree to return in such situations, further highlighting the effort they were prepared to put into adhering to the protocol, not all parents wanted to return for this visit. This was particularly, but not exclusively, true for families who lived a long way away, had other children, or if both parents worked. Cara told me that these parents knew that their child was not allergic as they ate the food with no signs of reaction, and for that reason they considered the journey and time that was involved was too onerous. She felt that asking parents to attend for these challenges could be viewed as unreasonable:

It's asking people with three kids, one of whom is six months old, to travel from Newcastle [as an example] several times to have a challenge for a food that they're eating daily. You know when you say it out loud it is ridiculous.

[Cara, Staff 07]

Thus the design of the trial, in which investigators were striving for robust outcome measures, initially resulted in reduced follow-up adherence. However, once EAT staff realised that a significant number of false positive results were likely to be obtained and that adherence to this aspect of the protocol was likely to be poor, they amended the protocol to allow children to undergo a shortened food challenge at the time of the skin test. They recognised that having the most scientifically robust procedures in the protocol was pointless if an insufficient number of parents would adhere. By making a small

⁵¹ Skin testing provides an indication of tolerance or allergy; a positive skin test is suggestive of allergy whilst a negative skin test suggests tolerance. However, the definitive gold standard test of allergy or tolerance is whether a child can eat an appropriate sized portion of the food without symptoms of reaction.

modification to the protocol they were able to maintain the scientific rigour of the assessments whilst improving follow-up adherence.

7.6.2 *The field of infant feeding and adherence*

In Chapter 6 I argued that the underlying philosophy of the field of infant feeding, which involved delaying giving young children allergenic foods, had important implications for trial recruitment. Given that young children in the UK were not generally given allergenic foods such as peanuts, nuts and sesame, and these products were often banned in schools and nurseries, intervention adherence was also influenced by this field.

Parents whose children had been randomised to the control arms of LEAP and EAT often commented that, because it was not usual practice to give small children allergenic foods, particularly peanut, adhering to their allocated group was relatively easy:

HF: ...and how have you found avoiding peanut?

Olivia: Um, actually that's not been difficult, I think. Um, the nursery that he goes to, they don't have any nuts in the nursery at all. They're very, it's banned completely.

[Olivia, L3MC]

Whilst most parents in the control arms found adherence easy, parents whose children had been randomised to the intervention arms had more difficulties. Zoe told me that parents quite often reported difficulties with adherence once their children went to nursery or school, as the policies of these institutions tended not to allow children to consume peanuts or sesame:

A lot of them have issues with nursery [...] a lot of the nurseries don't allow nuts so they can't give them Bamba [peanut] snacks or peanut butter [...] so it's an issue because a lot of parents have gone back to full time [work], so they can only get [peanut] into them maybe a couple of

times a week [the protocol requested three times a week], because in the evenings the kids are tired. [Zoe, Staff 14]

Although it was usual UK practice to avoid giving young children allergenic foods such as peanut at the time the trials were being conducted, the same was not true in other countries. Parents who came from African countries, where peanut containing foods were often frequently consumed, told me that they faced considerable difficulties when their children had been randomised to the control arms. Whilst avoiding peanuts in their own homes was possible, Ada told me that constant vigilance was required when they visited family or friends from similar cultural backgrounds, and particularly when visiting their home country:

In [my home country] there's peanuts everywhere, you know, and it's really difficult, and then he sees everyone, they boil it, roast it, we do everything there, and everyone's eating peanuts and he wants to join, and he doesn't understand that his mum has, my mum will tell him, your mum has, she's just, she's sold you out so you can't have peanuts.

[Ada, L22MC]

Thus, the differing philosophies of the field of infant feeding and the trials, and particularly the influence that the practices of these fields had within society was relevant to adherence. The philosophy of the field of infant feeding had been adopted by many schools and nurseries which were responsible for providing food for children and also for maintaining their safety. The sphere of this field's influence was far greater than that of the trials, and thus parents of children who attended nurseries and schools, particularly on a full time basis, did not always find adherence easy.

7.7 Conclusion

Adherence in LEAP and EAT was influenced by the philosophies or, in Bourdieu's (1990) terms, collective habitus of a variety of fields and by the interaction between these fields. The field of infant feeding clearly played a role. Whilst the philosophy of avoiding giving young children allergenic foods such as peanuts facilitated intervention adherence for most parents whose children were randomised to the control arms, it had the reverse effect on those whose children were randomised to the intervention arms, particularly if children attended nursery or school.

The philosophy underpinning the field of parenting exerted a similar influence on adherence as was evident for recruitment. Parents justified many of their adherence behaviours in terms of protecting and doing their best by their children. However, one difference was apparent. If parents felt that enrolling their children in the trial would have a detrimental effect on them then they found it relatively easy to decline the invitation to take part, but once they had enrolled in the trial, some parents experienced a role conflict that was particularly evident in the early phase of their child's participation. Parents' personal habitus, often the result of their upbringing, predisposed them both to want to contribute to society and to conduct the activities to which they had agreed to the best of their ability. They thus felt that they should try hard to adhere to all aspects of participation. If adherence seemed to be causing their child to suffer, however, these values contradicted their parenting habitus that they must protect their child from harm. Whilst parents always resolved this conflict in favour of protecting their child, it was not always an easy choice for them to make, and the staff played an important part in helping parents in this regard.

The specific conditions of the trials' fields were clearly relevant to adherence. The decisions that were made when designing the trials and that continued to be made by the investigators once the trials were underway were important. The trial staff made their expectations of adherence clear even before children had been enrolled on the trials and these expectations seemed to take the form of an informal contract that was proposed by the trial staff and accepted by the parents. Although parental motivations for accepting this contract varied between those who wanted to contribute to society and those who wanted to gain expertise in caring for their child's health, with respect to adherence I could find no evidence of Titmuss' (1970) assertion that societal benefit models of participation in prosocial healthcare activities are superior to personal benefit models. Whilst parental views of the need to contribute to society certainly drove their diligence in adherence, personal benefit appeared to have an equally, and in some cases, greater, influence.

Once participation was underway, trial staff continued to influence adherence by educating, encouraging and negotiating with parents. Whilst their goal was to promote adherence, at times the approach they took actually reduced intervention adherence. This occurred both consciously, when staff 'gave permission' for parents not to adhere, and unconsciously when the encouragement they provided to parents who were not fully adhering was misinterpreted as a signal that adherence was of limited importance. These issues are explored further in the following chapter, in which I present the results relating to retention in LEAP and EAT.

Chapter 8: Reciprocity and relationships: retention in LEAP and EAT

At the time I collected data for this study LEAP was in the fourth year and EAT was in the second year since initiation. Of the 640 children who had been enrolled in LEAP, five (0.8%) had withdrawn or been lost to follow up for a duration that led LEAP investigators to assume that they had been withdrawn. Of the 700 children enrolled in EAT, 17 (2.4%) had withdrawn. Thus, although the trials were still ongoing, withdrawal rates at the time of the study were low compared with the 20% that is considered to be an acceptable attrition rate (Sackett et al. 2000; Fewtrell et al. 2008).

When thinking about trial retention I had several questions that were not readily answerable with the existing literature. Why did parents continue participating in these longitudinal non-therapeutic trials? Were the good rates of retention attributable to the trial staff implementing successful retention strategies, or were the parents themselves particularly motivated to continue taking part? Were there differences in the cases of the few parents who chose to withdraw? Although both trials had excellent retention rates, parents had only been participating in EAT for a maximum of fifteen months, yet the rates of attrition were about three times those of LEAP in which families had been participating for a minimum of a year and a maximum of four years. As families participating in LEAP had had a greater duration over which they could have withdrawn I also wondered whether differences existed between the two trials that made it more likely that parents would withdraw their children from EAT than from LEAP.

In exploring these questions I draw, as in previous chapters, on Bourdieu's (1977; 1990) concepts of field, habitus and capital, and on the notions of social cohesion and reciprocity that are integral to Titmuss' (1970) Gift Relationship. I consider whether

parents' original motivations for participation influenced the choices that they made to continue taking part or withdraw their children from the trials. I also compare and contrast the two versions of exchange or reciprocity that Bourdieu and Titmuss propose, and explore whether either was superior in promoting trial retention.

The majority of parents who were interviewed for this study had children who were still participating in the trials, although I did interview one parent who withdrew from LEAP and two parents who withdrew from EAT. Given the small number, the conclusions that can be drawn from the data provided by these three interviews are limited, although they offer useful insights into the experiences of a group of individuals who are not easy to access. To encourage a more detailed understanding of the experiences of these three parents, I have portrayed the data from each of their interviews in greater depth, a method that has been successfully used by others (see for example Lawton 1998; Snowden et al. 2007). As I will go on to show, the reasons these parents gave for the early termination of their child's participation in the trials bore similarities to the themes identified in the data gathered from families who continued with participation. These parents' stories are presented within the themes for which their rationale for withdrawing most closely relates.

In addition to the parents who withdrew their children from LEAP and EAT there were also some 'near miss' withdrawals. These parents had either considered withdrawing their children but decided to remain, or had been lost to follow up for a period of time but then re-established contact and continued their child's participation. Nine of the families who participated in the interviews said that they had considered withdrawing from the trials but subsequently changed their minds, although only one parent had directly discussed withdrawing with the trial staff. During data analysis it was thus

possible to consider the experiences of parents who had thought about withdrawing their children from the trials but had ultimately decided not to. It was also possible to make comparisons between these parents and those who did withdraw.

In the remainder of the chapter I present the data regarding retention in LEAP and EAT. I begin by explaining how Titmuss' view of a social contract, and parents' habitus, positively influenced retention. Building on the notion of social capital that I introduced in the previous two chapters, I highlight its relevance for retention, not only in terms of parents continuing to facilitate their child's participation, but also with respect to the approaches that staff took to promoting retention. Finally I describe how structural aspects of the trials' fields were relevant to facets of participation that, whilst being more practical, were equally relevant for retention in LEAP and EAT.

8.1 Fulfilling the contract

When I asked parents why they continued to facilitate their child's participation in LEAP many seemed surprised by the question.⁵² They said that, when they agreed to take part in the trials they had accepted that this meant taking part for the relevant duration. They felt that the time and energy they had invested in the trial and that the trial staff had invested in them would be wasted if they withdrew before the final visit. Alison, who enrolled her daughter in LEAP because she felt it was important to contribute to society, gave me a fairly typical, although perhaps more emphatic, response:

Why on earth would I pull out? I can't think of any reason why I'd pull out. So you're doing it to help people, if I pull out its just complete nuts.

⁵² I did not ask EAT parents directly about the reasons for their continuing participation as they had only been participating for an average of three months (1.75-4.5 months) at the time of the interviews. However some also volunteered views about their future participation that were analogous to those expressed by LEAP parents.

So if hundreds pull out the whole study falls over. It's pointless.

[Alison, L6MI]

Alison's reason for continuing to facilitate her daughter's participation in LEAP reflected her original, altruistic, motivation for participation. She also drew on her understanding of research when describing why she continued to take part. This understanding was shared by many other parents, including Charles, who enrolled his son in LEAP because he considered the trial to be investigating an important question:

If we don't, er, go to term with it, they'll probably take that as a complete void. All that we've done will probably be binned, in terms of statistics, and then, well, [the trial staff] can't really conclude on anything over five years. So it would be completely wasted. So I think there's that sense of, oh we've got to achieve [trial completion] basically, even if he's just in the control group [because] you can't validate the peanut group if you're not having the control group.

[Charles, L19FC]

As the interviews with Alison and Charles highlight, parents recognised that if they withdrew their children early then the ability to determine which of the two interventions was most effective would be reduced. Furthermore they understood that if substantial numbers of parents withdrew their children then the trial might not reveal meaningful or useful findings. Parents thus considered that withdrawing their children was incongruent with one of the reasons that they chose to take part: to help further understanding of the causes of food allergy. This belief also led parents who thought about withdrawing to persevere for some time after first experiencing doubts about their child's participation. Regardless of their ultimate decision to continue with or withdraw their child from the trials, all but one of the parents who thought about withdrawing explained that the final decision was not an easy one. As Lesley, who withdrew her daughter from EAT after she

had an allergic reaction explained, terminating her daughter's participation prematurely did not sit easily with her knowledge that to do so would negatively affect the trial's final outcome:

For their research purposes it would have been probably quite handy to have kept her in the study [...] I feel disappointed that I can't carry on, but that's just how it is. [Lesley, E34MIW]

The data suggest that the 'societal contract' that Titmuss (1970) considers to be important for participation in prosocial healthcare activities and that was relevant to parents' recruitment and adherence decisions also played a role in retention. Parents felt that adequately fulfilling the contract they had entered into when they agreed to take part depended on their child remaining in the trial until its completion. Their surprise at my asking the question suggests that these views were part of their habitus, a 'taken for granted' value (Bourdieu, 1977) that, upon further questioning, appeared to reflect the values that their own parents had instilled in them.

Although parents continued to take part so that their contribution would be of value, there were occasions when parents came to doubt the usefulness of their contribution. As I discussed in the previous chapter, not all parents found adhering to the intervention easy. Several parents whose children had been randomised to the intervention arm of the trials but were not managing to consume the recommended quantities of the foods questioned whether their child's continuing participation was worthwhile. Drawing on their knowledge of medical research, they assumed that the trials' rules of participation would be stringent and that they should follow them meticulously. When they were not able to adhere they believed that they were not fulfilling the contract that they had agreed to when they consented to their child's participation and were thus not making a

useful contribution to the trials' goals. As Ed explained, this led parents to contact the trial staff to say that they wanted to withdraw because:

They think they've let us down by not doing what they're supposed to [...] and they feel wretched and useless. And then part of it is saying well, look, you know, it's not the end of the world. Just be honest about what you're doing. [I tell them that] we learn as much from our mums who have struggled with this, and if not more, than we do with our mums who have found it all plain sailing. And they say, oh that's brilliant. And I say would you be willing to keep going in the study? And they usually say yes. [Ed, Staff 04]

As his quote demonstrates, parental perception in this regard was misplaced. The 'rules of the game' (Bourdieu and Wacquant 1992) for this specific research field had been modified. The staff viewed the trials as pragmatic and, for them, retaining participants until the primary outcome measure could be obtained was more important than rigorous adherence to the protocol if the two were mutually exclusive. Both staff and parents told me that, once parents understood these modified rules, the reassurance that imperfect adherence was acceptable had a positive effect on retention. By explaining the modified rules and negotiating with parents the staff were often able to facilitate their continuing participation. This strategy was one of several approaches that the staff took to trial retention.

8.2 Staff approaches to retention

Marcellus (2004) argues that trials often suffer from poor rates of retention because researchers view attrition as inevitable and thus place little emphasis on retaining participants. This did not seem to be the case with LEAP and EAT staff. During protocol development the trials' sample sizes were calculated to allow for differences between the intervention and control groups to be detected with sufficient power even with 15% (EAT)

and 20% (LEAP) attrition. Yet whilst the staff knew that some attrition would not affect the trials' outcomes, it seemed to me that they felt that not even one participant should be lost to follow up or withdraw without good reason.

I asked LEAP and EAT staff whether, when they began working on the trial, the importance of retaining participants had been discussed with them but, regardless of the time that had elapsed since their employment, they told me that they did not remember this to be the case. Reflecting Bourdieu's (1977) notion of a shared habitus this value was deeply embedded and staff appeared to adopt, and often practice, the philosophy subconsciously. The need to retain participants was an integral part of their teams' values and, as the following extract of an interview with Rachael illustrates, new staff learnt about the importance of retention by observing the attitudes and behaviours of the existing staff:

HF: It sounds like quite a lot of effort is put into [retaining participants]. What's the driver behind that?

Rachael: We don't want to lose anyone.

HF: You don't want to lose anyone?

Rachael: Yes, yes.

HF: And who drives that?

Rachael: I think there's sort of a team honour [...] my impression when I came was very strongly 'we don't want to lose anyone'. [Rachael, Staff 09]

Contrary to the concerns expressed by parents who worried that their child's participation was not valuable, staff placed great value on each family's continuing participation. They told me that the huge resources they had invested in recruiting

participants and the time and effort that parents had put into participation meant that it was essential to retain sufficient numbers to achieve meaningful results at the end of the trial. As I discussed in the previous chapter, the valuable data produced by children's participation in the trials was a source of social capital for the staff, both in terms of the contribution it made to advancing knowledge and the potential for this to advance their careers. In their efforts to retain participants LEAP and EAT staff employed a variety of strategies.

8.2.1 Retention strategies

During my observations I noted that, in a similar approach to that taken to facilitating adherence, staff from both trials adopted the role of 'detective' and were proactively reactive in their retention strategies. They devoted considerable resources trying to minimise attrition by, for example, spending substantial time contacting parents with whom they had lost touch, thinking of innovative ways to re-establish contact, being alert to participants who might be at risk of withdrawing, and providing support to parents who had discussed withdrawing. It seemed that families were given as much assistance as they required to facilitate their ongoing participation. I asked Rachael whether requests for help with continuing participation had ever been refused, but she could not think of an occasion.

The emphasis that staff placed on retaining participants meant that, during the interviews, several of the EAT staff expressed concern that a lack of financial resources limited the time they were able to devote to implementing retention strategies. Although they provided assistance to parents who contacted the study to ask for help, they had learnt that, for some parents, non-adherence to the questionnaires could be an early sign that a parent was considering withdrawing their child from the trial. However, they did

not have the resources to identify and contact these parents as frequently as they would have liked. This was frustrating for them because, as Douglas explained:

Ultimately the patients are the really important part, and if we can't support them to be in the study in a genuine way then we haven't got a leg to stand on. They're a precious bunch of children.

[Douglas, Staff 06]

Although each family's continuing participation was highly valued, LEAP and EAT staff described the importance of balance in retention strategies. If parents contacted the trial investigators to say that they wanted to withdraw their child, the staff would often discuss whether they could support them to continue participating. They told me that there were instances in which they did not consider this approach appropriate, if parents withdrew due to bereavement or serious illness in close family members, for instance. Cara explained that, although the trial team wanted to retain as many participants as possible, it was more important not to cause families undue stress:

I feel very strongly that I don't want to push people in that situation [when a parent's parent had been diagnosed with a serious illness and they decided to withdraw]. You know, whatever we're doing is not the most important thing in these people's lives and, you know, I'm not willing to make life harder for them when things are clearly hard already.

[Cara, Staff 07]

Even when they felt it was appropriate to make contact, the staff explained that their ethical responsibilities meant that they must adopt a sensitive approach. They recognised the potential for the strategies that they used to be coercive, and tried to ensure that parents did not feel pressurised into continuing their child's participation. As Katerina told me:

I'd feel bad if they were like, I can't withdraw because obviously they're ringing me and pestering me to stay, but it was more a case of, she actually felt reassured and was glad that we'd spoken and wanted to continue. [Katerina, Staff 15]

8.2.2 *Customer service*

In addition to overt strategies to promote trial retention several staff discussed the importance of '*customer service*' [Rachael, Staff 09] in this regard. This was also apparent during my observations and I noted that staff tried to ensure that the participating families had as pleasant an experience as possible. The unit was well equipped with toys, arriving families were warmly welcomed, and staff tried to balance making efficient use of parents' time with ensuring that children felt comfortable with the new environment and understood the procedures that they would be undergoing. Parents commented on the pleasant environment, highlighting that it made them feel '*respected and cared for*' [Jemima, L2MI]. I recorded in my field notes that even small changes to the environment that had the potential to shape parental perceptions of the trials resulted in lengthy discussions to minimise any negative impact:

Some of the staff were talking about a new policy that hot drinks were not allowed on the unit due to concerns about the potential for mugs of hot liquids to be spilt and burn someone. One staff member said that it gave the wrong impression of the trials and the NHS if parents couldn't be offered a cup of tea when they had travelled for hours to attend. Another staff member began looking online for cups with lids that could be used instead of the mugs they currently had. After some discussion they decided that they needed to have a meeting with the senior staff to discuss the new policy further. [Field notes, 23rd February 2011]

I also noted several instances where, when mistakes had been made, the staff quickly implemented measures to ensure the same error could not happen again, as the following excerpt of my field notes illustrates:

Ed made a phone call to a parent who had a query about her child's blood results. He phoned the mum and after the introductions said that he understood that she had a question and apologised for not getting back to her more quickly. The mother obviously said that someone had contacted her already because Ed said, 'oh my illustrious colleague contacted you, I hadn't realised. So now I'm bothering you again, I'm so sorry – but whilst I'm on the phone, how is everything?' After a short discussion and another apology for the duplication of contact the conversation finished. After replacing the receiver I observed Ed compose an email to the other staff saying that if they dealt with parent queries they must let other members of the team know so that parents weren't contacted on multiple occasions.

[Field notes, 8th February 2011]

During my observations I noted that the staff also conveyed their gratitude for parents' continuing participation more overtly:

Hugh thanked a mother for sticking with the study, saying it couldn't be easy, particularly receiving frequent phone calls. The mother said they were perfectly happy to keep going and valued the support that they had received during the calls.

[Field notes, 25th October 2010]

LEAP investigators also communicated their gratitude more extensively in the newsletters that were sent to participating families approximately once a year. Each newsletter thanked parents for their participation and re-iterated the importance of the families' contributions, as this excerpt from a newsletter that was sent to parents after recruitment had been completed illustrates:

The most heartfelt thanks is reserved for you, the parents of LEAP children. This gift you have given us – the gift of your family’s participation – is one that we hold very dear. Without you there would be no LEAP study, and without you we would be no closer to solving some of the mysteries of peanut allergy.

[LEAP Newsletter Issue 2 – June 2009]

This letter also reflects that notion, that, since the publication of Titmuss’ (1970) *The Gift Relationship* the term ‘gift’ is frequently used in relation to participation in prosocial healthcare activities. As I outlined in Chapter 3, in these contexts the term gift may be used in a multitude of ways, but in this letter it appeared to acknowledge both the effort that parents had expended by participating in the trials, and the value of that effort to the trial staff and the goals of the trial.

The emphasis that staff from both trials placed on providing good customer service to the participating families seems to have been the precursor to an aspect of retention that, as I show in the following section, was particularly relevant to minimising attrition: the building of relationships between parents and staff.

8.2.3 Relationship building

Within the context of LEAP and EAT, parents and staff came together to try and advance knowledge about how to prevent future generations of children developing food allergy and, in many instances, with the hope of improving the health of participating children. Their relationship thus developed out of necessity: the researchers wanted access to the data that parents could provide through facilitating their children’s participation in the trials and the parents wanted to contribute to this goal and to access the expertise that they needed to care for their children. Thus for staff and parents it was essential to develop a relationship that permitted information giving and advice exchange, i.e. to

create the conditions through which social capital is accrued (Bourdieu 1986). Yet the rapport that existed between staff and parents often belied the necessity of the relationship. The staff spoke warmly of the dedication of the parents and the parents commented on the helpful and personable nature of the trial teams, using terms such as '*delightful*' [Naomi, E45MI], '*brilliant*' [Nicole, L24MI] and '*like a friend*' [Keira, L15MC] to describe the staff.

Reflecting the approach that staff took during recruitment and adherence to try and engage parents in understanding the rationale behind the trials' activities, during my observations I noted that staff from both trials seemed to hope that parents would be interested in and understand all aspects of participation, from their own contribution to the overall trial progress. I observed staff updating parents on the developments within LEAP and EAT and spending considerable time explaining aspects of the protocol design. They also openly discussed situations that might inconvenience the participating families. For example when (as described in Chapter 7) the EAT protocol required children to undergo food challenges to foods that they were eating regularly, staff took time to explain to parents the inexact nature of diagnosing food allergy and the differences between what is acceptable in clinical practice and what is acceptable in research. In this way they hoped to, and were often successful in, engaging parents with aspects of the trial that might otherwise seem incongruous.

Parents frequently mentioned the importance of the relationship that they developed with the staff for their continuing participation. They highlighted the store they set by the friendliness of the staff and of talking to and seeing the same staff members for the duration of their participation. Bea, who enrolled her eldest son in LEAP because she was interested in the research question, told me that, because she had been happy with his

participation and had got to know and like the staff, she had decided to enrol her second son in EAT. She felt that she had developed a relationship with the staff that would be difficult to break by the early withdrawal of her children from the trials:

HF: [...] and have the study staff on either study, both studies, done anything to kind of keep you and other parents in the trials do you think?

Bea: Um, well I think they're very nice if that sort of, I mean the fact that they're very friendly, and you sort of feel that, like it probably is part of the motivation that I would be letting them down personally. It wouldn't just be sort of, if it was just an internet study I think it would probably be easier to drop out because you would at some point just get bored of filling in forms, but because they're, you know I've met the people and they're very nice and talked me through it, and you know they, they obviously have a, a commitment to the study, I'm sure that, I'm sure that's probably influenced me. [Bea, L26MC&E56MI]

LEAP and EAT's differing designs influenced the relationships that developed between the staff and parents. LEAP staff and parents told me that the regular phone calls helped them to get to know each other and to feel comfortable discussing any problems that the parents may be having with participation. LEAP families also received festive 'holiday season' cards, small gifts were given to children when they attended the visits, and newsletters were sent to the families at yearly intervals. These incentives have been found to be important to retention, although the effectiveness of different strategies appears inconsistent. Strategies that promote retention in one trial have been found to be ineffective in other trials (Robinson et al. 2007; Williams et al. 2008; Booker et al. 2011).

Data gathered for this study may help to explain this inconsistency. When I asked LEAP parents whether the trial staff did anything to try to keep them in the trial, a few mentioned the newsletters, but only Yvonne, who worked in clinical trials herself, made reference to the presents that the children were given. This omission on the part of other parents may be because, as Yvonne explained, although her prior knowledge meant that she understood these gifts to be part of the retention strategies that trials often employed, the way that the trial staff implemented them did not make her feel as though she was being incentivised to continue her son's participation:

They've given little gifts to [my son] when he's gone and done his things [...] they get a, a birthday card or a Christmas card. There was a card that came in the post and I think maybe it was Christmas card and I thought that was a really lovely touch. And it, but I know that it's to keep um people involved in the trial because I know when I've seen the applications [for research funding] they always say, yeah these little incentives to keep them, so I know that that's what it is, but I know it's done well and it's good. [Yvonne, L3MC]

Thus it seems that it was not the retention measures themselves that were successful, but rather the message that they conveyed. Parents viewed them as part of the relationship that they had developed, an expression of friendship and gratitude for their contribution. Coupled with the frequent phone calls these measures helped the development of bonds between parents and staff that promoted retention to LEAP.

EAT parents were as positive about the friendliness and enthusiasm of the EAT staff as LEAP parents had been about LEAP staff. Rosie, who had recently enrolled her daughter in EAT, described her initial visit to the trial site as a positive experience:

I think it was just such a jolly place, wasn't it? And everybody, yeah, it was a really vibrant place I think, and [the staff] just exuded enthusiasm,

and you came away quite buoyant actually, thinking, oh yeah, I'm really
doing something worthwhile here [Rosie, E54MI]

However, EAT's design meant that there was substantially less potential for the staff and parents to build relationships than was the case for LEAP. Owing to the number of participants and the level of available funding, data were gathered by online questionnaire rather than phone calls. Unless the parents contacted the trial staff with concerns about their participation or the trial staff contacted parents because they were not completing the questionnaires, the amount of personal contact between EAT staff and parents was limited to the three scheduled visits over the course of three years.

Additionally no gifts or newsletters were provided because, the EAT staff explained, of a lack of financial resources. Not only was there insufficient funding to cover the material costs of providing gifts for 1300 children, their staffing levels did not permit them to devote much time to proactive retention activities because they were already working at full capacity to ensure successful recruitment. Thus for EAT staff and parents, the potential to build on the good relationship that began at the first visit was restricted.

These data highlight that relationship building was influenced by the specific conditions of the trials' fields and the availability of necessary resources. In the previous section I described the importance that the staff placed on identifying parents who were finding participation difficult so that they could be offered help or assistance before the trials' activities became such a burden that they felt they had to withdraw, i.e. before their relationship with the trial deteriorated to an extent that could not be rectified. In LEAP, which was proportionately better funded than EAT, this was made possible by the frequent phone calls that were incorporated into the protocol. As Brueton et al. (2011) also found, the importance of regular staff-parent communication in retaining

participants was clear, allowing parents and staff to develop a relationship in which concerns or problems could be discussed and rectified. However, EAT did not have the same level of personal contact and the difference in budgets or, in Bourdieu's (1986) terms, the availability of economic capital, limited their ability to build supportive relationships. This finding may, in some way, account for the difference in retention rates between the LEAP and EAT.

The relationship that developed between parents and staff was also relevant to another aspect of trial participation. In the following section I will explore the role of inclusion benefit (Lantos 1999) on retention in LEAP and EAT.

8.3 Benefit and reciprocity

As I described in Chapter 6, some parents, particularly those whose children had an underlying health condition that they felt unable to manage by accessing standard healthcare, hoped that trial participation would allow them to obtain expert care for their child. As I go on to show, in the same way that the potential for benefit was relevant to trial recruitment, actual benefit was relevant to retention.

8.3.1 *Benefit*

The majority of parents who had hoped that their child would derive benefit from participation were satisfied that this had been obtained and, in some instances, had exceeded their expectations. David, who enrolled his daughter in LEAP because he and his wife felt unable to get the assistance they needed to care for her food allergies from their local healthcare providers, felt his expectations had been met:

HF: Have the benefits to participation that you anticipated,
 have they happened?

David: Yeah, cos we know exactly what [my daughter] is allergic to. Er, quite recently we've had like, a sort of really in depth [trial visit] where they've like took samples of her blood, and now she's allergic to dog hair and all sorts [...] and she gets nutritional advice. These things we wouldn't have known about. [David, L8FI]

Even parents who had not expected to derive benefit described how they had found participation useful. Marianne enrolled her son in EAT because she considered the trial to be answering an important question. She explained that, although she had not anticipated any personal advantages to participation, she was pleasantly surprised to find that there were:

When we went with [my son] he had very, very bad cradle cap [...] and I was telling the nurse, oh it's really, really bad, oh look at it, it's dreadful, I hate it, you know, and I've been to the doctors and they've given me this shampoo. And she said oh I'll get our dermatologist to come and have a look. [The dermatologist] just happened to be in the room, came over, gave him some cream, cleared it up an absolute treat. So we saw a real direct benefit on that day for us taking part. [Marianne, E42MC]

The majority of the benefits that parents described related to the advantages that access to a multidisciplinary team of specialists in allergic disease afforded and the ability to see a paediatric allergy consultant was an often cited benefit. This suggests that, as for recruitment, retention was influenced by the field of healthcare, specifically the lack of paediatric allergy services in the UK at the time that these trials were being conducted. Parents explained that, even if their GPs had referred their children to a paediatric service, they might have been seen by a more junior doctor or by a paediatrician without such specialist knowledge. They considered that these physicians would lack the expertise possessed by the trial investigators as both specialists within paediatric allergy and as

researchers who were likely to be at the forefront of their field. LEAP parents also felt that they would not have received the same level of support as had been made possible by the scheduled phone calls.

Sharon, who enrolled her son in LEAP because she was not able to obtain the help that she needed in caring for his eczema and food allergies from her local services, told me several times during the interview how the expertise she had obtained through participation had been substantially better than the care she had received outside of the trial. When I asked her whether she had ever considered withdrawing her son from LEAP she told me that she had not. When I asked her why this was she explained that she was still obtaining the expertise she required:

They ring me every month, they're still advising, they're still helping me. They're, they have a general interest in my son's health, which I think's nice, you know he's not just a number. They actually genuinely care, and I think that's, that's nice.

[Sharon, L11MC]

This view was reflected by many other parents whose original reason for participation reflected a hope for personal benefit. Bourdieu (1977) suggests that practice is influenced by individuals' positions within a field and their desire to advance their positions by obtaining capital. In the context of the trials, participation permitted parents access to a source of social capital. The expertise that trial staff possessed led to improvements in their child's health, and thus, by doing their best for their children they were viewed as 'good parents' within the parenting field. The opportunity to access specialist services that were not easily available outside the research context also meant that, even if their children's need for specialist healthcare resolved, parents considered that continuing to take part in the trials was worthwhile. In addition to helping to advance scientific

knowledge, their ongoing participation offered 'insurance' against a future need for specialist healthcare.

Retention was not only influenced by parents' views of the opportunity for benefit, the trial staff also needed the families to continue providing the data that the success of the trials relied upon. Thus the relationship allowed both parents and staff to accrue social capital in the form of the resources that they needed to achieve their goals (Bourdieu 1986). As their desire for access to these resources was ongoing continuing the relationship was important. As I describe in the following section, this led to the development of an interdependent relationship that was underpinned by reciprocity.

8.3.2 Reciprocity

As I discussed in Chapter 6 and earlier in this chapter, parents felt that they and their families had benefitted from previous generations of research participants' willingness to contribute to society. By remaining in the trials until the final data had been gathered, parents considered that they would be taking part in a 'relay' of altruism, in this instance by helping to ensure the evidence produced by the trials would extend the current understanding of the causes of food allergy. This version of reciprocity is reminiscent of societal benefit model of exchange discussed by Titmuss (1970).

An alternative notion, more in line with Bourdieu's (1977) version of exchange was also evident. Even before the relationship began both parents and staff hoped that participation would provide an opportunity for an exchange of resources that would benefit them personally: parents wanted access to expertise and staff wanted access to the data that the children's participation would afford. Bourdieu (1977) suggests that, in exchange relationships, resources are 'bartered'. Although bartering for capital in LEAP and EAT was not necessarily overt, through the relationship that developed and the

negotiations that took place, exchanges did occur. Parents attended the trial visits, conducted the trial activities and provided staff with the information they required, and in return staff provided expertise that led to improvements in the child's health. In these instances reciprocity resulted from a direct exchange of resources that were valuable to the other party.

Trial retention was influenced not only by the prolonged need that parents and staff had for this exchange of resources, but also by their personal values that give and take are necessary in relationships. Whilst most parents expected their child to benefit from participation, they also felt it was essential to repay this by continuing to take part. Earlier I highlighted that a prime reason that Sharon continued to take part in LEAP was because her son was still benefitting from their participation. However, like many other parents she told me that *'to get that help you got to, you've got to give some to get back'*.

[Sharon, L11MC].

The staff also considered that give and take were important in the relationship that they had with parents. During the observations I noted that staff frequently provided parents with help and support in caring for their child's health and, recognising the scarcity of the expertise that they had developed over the course of their careers, also gave advice on allergic health conditions that were not related to the trials outcomes. They rarely refused requests for help that were not directly relevant to the trial protocol, even if they were not terribly convenient. As this excerpt from my field notes shows, they also gave help and advice that had not been directly requested:

When examining a little boy who was attending the unit for his 30 month visit Hugh asked the mother if her son had been well recently.

The mother mentioned that he had had some diarrhoea and Hugh spent

about five minutes asking lots of questions about it: how long it had been going on for, if anything made it better or worse, any illnesses that had triggered it, and whether the child was otherwise well. Hugh was very sympathetic and said it sounded like toddler diarrhoea. He spent another five minutes explaining this condition, how to manage it and when to seek additional assistance. [Field notes, 27th July 2010]

The design of the trials, in which parents were asked to report any health issues that their child was experiencing as part of the safety data that were needed, facilitated this advice giving and thus the reciprocal relationship. The staff also explained that the responsibilities their professional qualifications endowed meant that it was hard for them not to help parents and children to attain the best health that they could. Hugh felt that:

You have to see the whole thing as a package, to do them a decent service as well. And this does impact on health, if they have uncontrolled asthma and they're peanut allergic they are at greater risk for severe reactions, so we can't, if we document those conditions we need to make sure the GP actually acts on them [...] if you're on the floor seeing the patient it's near impossible not to provide some extra advice.

[Hugh, Staff 03]

This 'spilling over' of clinical care into research practice has been identified by others (Miller et al. 2008; Hallowell et al. 2009; Lawton et al. 2011) although generally within the context of therapeutic research. Data from this study may help to explain why this occurs. Lawton et al. (2011) argue that staff experience role conflict when conducting trial activities. However, for LEAP and EAT staff there does not appear to have been any conflict, rather they considered that their professional qualifications bestowed them with responsibilities that existed *regardless* of their role as clinician or researcher. Their personal values meant that they also believed that it was important to provide assistance to families in need, and that it was right that families who were helping to advance

knowledge should receive these small benefits in return for their assistance with the trials' goals.

The reciprocity that was evident may reflect the non-therapeutic nature of the trials. Perhaps because the trials were being conducted outside of a 'normal' healthcare interaction the staff-parent dynamic that I observed was more reminiscent of a partnership than of a hierarchal doctor-patient relationship; the balance of power appeared to be equally distributed. Whether this parity of power facilitated reciprocity or was a result of the reciprocal relationship is hard to know, but the sociodemographic characteristics of the parents may also have been relevant. Most of the parents who I interviewed were highly educated and many had medical or scientific backgrounds. Bourdieu (1990) argued that the practices of individuals with similar backgrounds are often complementary because there is strong concordance between their habitus, or values. Similarities between the backgrounds of parents and staff may have resulted in similar values, which, in turn, facilitated reciprocity.

In the preceding paragraphs I described two relationships: one in which the exchange occurred according to a personal benefit model, i.e. where staff and parents directly benefitted from their ongoing relationship, and one in which the exchange reflected the societal benefit model, where parents continued to take part to contribute to society. Although I presented them dichotomously, in reality, and as was the case for recruitment, there was fluidity between these positions; they actually represented a continuum. Some parents began participation with primarily altruistic aims but came to recognise the relationship they were developing with staff was also beneficial for their children. Others began their participation wanting to obtain help for their children, but when their need for expertise dissipated they had become so caught up in the aims of the trial that they

continued participating to contribute to these. Many had dual motives both for their initial and their continuing participation.

Regardless of their original motivation, reciprocity was clearly important for retention.

This was particularly evident during an interview with Brigitte, who withdrew her daughter from LEAP and whose experience is presented in Box 2.

Brigitte: L28MIW

Brigitte and her husband moved to the UK a few years before their daughter, their first child, was born. Brigitte felt that she had some knowledge of research practices and was generally positively disposed to medical research, believing that everyone benefitted from the altruism of previous generations. She had never taken part in research before and did not know of anyone who had.

Soon after their daughter was born both Brigitte and her husband became very worried about her health. She had bad eczema and suffered abdominal discomfort that Brigitte felt was related to her diet. She considered that attempts to seek the help that she wanted from their local health services were fruitless and at that time Brigitte felt uncertain about the best way to care for her daughter.

No one [in my family] has a problem with allergies or dermatitis. I was complete, like, er, I didn't know what to do. What shall I give her? What kinds of foods? It was absolutely mad for me because she was suffering, she was about to introduce new food, I didn't even know what food, which food shall I give her, what food shall I avoid?

Brigitte heard about LEAP from a flyer that was posted to her home address, and immediately recognised the potential for trial participation to provide her with the help that she wanted. She was initially concerned whether giving her daughter peanut products would be harmful, but she discussed this with the trial staff, considered that she had received 'reasonable information' and felt reassured that there was unlikely to be any risk to her daughter. She and her husband made the decision to take part without advice from other family members, friends or HCPs, and the good reputation of the hospital that was hosting the trial contributed to their decision. Their main reason for participating was the potential to gain expertise that would lead to improvements in her daughter's health.

I really needed guidance from someone and the LEAP study promised advice from dietitian, er, what was described it was very like a personal guidance and you [could] contact the dietitian anytime, I can contact them anytime I want and that they will provide the tests for food allergy, and so I decided, yeah, I will let my child do this thing to help and I will benefit from the advice from the professionals. [...] If

someone is suffering and you are not getting help and advice you are ready to do anything.

When I asked whether the aims of the trial were also important to her Brigitte told me that the most important issue was that she received professional advice. Whether the trial or society also benefitted from their participation was much less of a concern for her, although she was pleased to be contributing.

At the first visit Brigitte was impressed with the trial staff whom she considered to be friendly and kind. She explained that she had hoped that her daughter could be tested for a wide panel of foods to which Brigitte thought she might be allergic, and had been disappointed that only a few skin tests were conducted. Despite this, she decided to continue her daughter's participation, and was still hopeful that she would be able to access the expertise she desired.

Her daughter was randomised to the intervention group but struggled to consume the full quantity of peanut. Brigitte said that she was a little confused that the staff were unconcerned by her poor adherence, but was happy to keep trying at her daughter's pace. However, over time she became frustrated with participation, particularly as her daughter's health did not improve and she still suffered with abdominal pain and eczema. Brigitte was unhappy with the quality and amount of advice that she received and described feeling increasingly dissatisfied, considering that the phone calls were very brief and did not give her sufficient opportunity to ask questions. She explained that a phone call during which the trial staff had not given her as much time and advice as she had wanted was the final straw. Although she agreed to participate *'for advice exchange, we give child for research and we have professional help'* she considered the relationship that developed was one-sided. Thus she decided to withdraw.

At this time I decided, oh I'm withdrawing my child because this is human life. The precious thing you have is children [...] but if you sacrifice your child, you can say that you sacrificed because you let them do this to your child, then you expect the best from them in exchange, and if they are doing, treating you in this way, then that's why I decided to withdraw.

After making this decision she emailed the trial staff saying that she was going to withdraw. She received a phone call from one of the trial staff *'trying to convince me to stay,'* but remained resolute in her decision. When I asked her whether anything could have changed her mind she said that the only factor that may have induced her to stay was if the quality and quantity of the advice had improved. I also asked about her views of research since LEAP and she said that she was now more suspicious of research. Although she would consider future research participation for her children, she would spend more time considering potential issues and would ask more questions prior to consenting.

Box 2: Brigitte, who withdrew her daughter from LEAP

As can be seen from Brigitte's story, although she had hoped for a reciprocal relationship with the staff she did not feel that this was forthcoming. After a few months of participation Brigitte decided to withdraw her daughter from the trial. She felt that the relationship was one sided. Whilst she was giving her daughter peanut and providing information about her diet and health, she considered that the trial staff were not providing sufficient help and advice to allow her child to benefit from participation. As her daughter's health was not improving, her goal for participation was not being met and she felt that continuing participation was pointless. Brigitte's story also highlights that, although the staff aimed to retain as many participants as possible and were prepared to go to significant lengths to achieve this aim, there were situations in which this was not possible: the reciprocal relationship had a boundary.

8.3.3 The boundaries of reciprocity

The reciprocal relationship that developed between parents and staff was discussed by staff and the sponsors of the trials in relation to a 'line' that should not be crossed. This is illustrated by a quote from Elsie, who worked for the organisation that funded and sponsored LEAP:

Elsie: Your site⁵³ goes, your staff goes above and beyond the duty, and above and beyond what we're actually paying you for, to integrate that into your clinic service, and to provide sort of this extra layer of patient care that's outside of the trial.

HF: Right, ok. And is that different to other trials [in your remit] would you say?

⁵³ Elsie had been a colleague when I worked on LEAP and thus referred to LEAP as 'your' site.

Elsie: Ah it, it is, and you know it's a fine line, but I would say
your site's done a very good job of staying on the right
side of the line. [Elsie, Staff 01]

The staff who worked directly with the families told me that it was important that both they and the parents understood that the role of LEAP and EAT was not to replace the standard primary care that the child required to maintain optimal health, as to do so would breach a metaphorical line. The breaching of this line was viewed as problematic for ethical and financial reasons. If the benefits of participation were too great then parents might feel coerced into continuing their child's participation when they otherwise might prefer not to. Moreover the resources allocated to the trials were only sufficient to permit the trial activities to be performed; they did not allow for the child's routine healthcare needs to be met.

Most staff and parents appeared to recognise both the existence of and the need for a 'line' within the reciprocal relationship even though this line seemed to both tacit and flexible. The line itself represented the boundary beyond which research became healthcare provision, and although this boundary was not clearly defined, it seemed generally to be well understood by both parents and staff. During the interviews and observations it was apparent that, although some parents sought care that was not covered in the protocol such as asking for a skin test for a 'non-protocol' food, or for advice regarding how they should wean the baby sibling of the trial child, few parents made significant demands for help that were unrelated to the protocol and their requests were generally met.

For a small number of parents, the boundaries of reciprocity and perhaps of the difference between healthcare and research were less well understood. During the

interviews the staff described how a few parents made requests for help that they were unable to meet. They told me that in such instances the parents were usually understanding but in the case of Brigitte, whose story was represented in Box 2, this was not the case. She had hoped for more assistance with caring for her child's health than the staff provided and, as Brigitte and the staff's understanding of the boundary between research and healthcare were divergent her goals for participation were not achieved. For Brigitte, the goals of the trial were much less important than her desire to obtain help for her daughter. Furthermore, her initial reluctance to withdraw despite concerns over her daughter's participation reflected a continuing hope for expertise rather than a commitment to the trial's goals. Ultimately this hope waned and, in doing so, her relationship with the staff deteriorated. When she did not receive the help that she wanted for her daughter she considered that the relationship was one sided and did not find the decision to withdraw her difficult.

Throughout this thesis I have discussed the dual contract that informed parents' decisions about participation in the trials and how they needed to juggle their 'parenting contract' to act in the best interests of their children, with their 'societal contract' to act as a good citizen. The reciprocal relationship that developed during the course of participation often facilitated both: by taking part they were contributing to society and the expertise that staff provided was often beneficial for their children. However, this was not universally true. In certain instances acting in the best interests of their child and contributing to society became incongruent. As I discuss in the following section, if parents deemed that participation was causing their child to suffer, then they questioned whether they should remain in the trials.

8.4 Harm

The values of the parenting field, to protect children from harm, were clearly evident in parents' discussions about their experiences of participation. When asked directly whether they had ever considered withdrawing their children from the trial, four LEAP parents said that they had. In addition to Brigitte, whose experiences were discussed in the previous section, Sally told me that her son's experience of blood taking was very traumatic and at that time she thought about withdrawing him, although her desire to contribute to the goals of the research meant that she decided to continue his participation but to monitor his future experiences. Lily had a strong belief that consuming peanut would prevent peanut allergy, but her daughter was randomised to the control arm of the trial. She explained that she intermittently asked herself whether she was placing her daughter at risk of harm, her primary concern being whether avoiding peanut was likely to result in her developing peanut allergy. However, she felt that there was still uncertainty as to the best way to prevent peanut allergy and, as she had no proof that avoiding peanut was harmful, she remained in the trial because:

Unless I know for a fact that [trial participation] is detrimental to [my daughter's] health, I will not withdraw. [Lily, L1MC]

When I began interviewing EAT parents I was surprised by the number who told me, before I asked them, that they had considered withdrawing. As the children of EAT parents that I interviewed had only been participating for a few months I had anticipated that few would have considered withdrawing.⁵⁴ However, six parents, proportionately almost four times as many as described having considered withdrawing from LEAP,

⁵⁴ Given their short duration of participation I had initially considered I would not ask EAT parents whether they had considered withdrawing. I amended this decision when the first few parents that I interviewed volunteered that they had thought about withdrawing their child from EAT.

explained that they had contemplated leaving the trial. In each case their reason for this reflected concerns about harm.

The children of all EAT parents who considered withdrawing due to concerns about harm had been randomised to the intervention arm of the trial. Parents told me that, soon after they began the weaning schedule their child's health or behaviour changed.⁵⁵ While the written and verbal information given to parents warned them about some changes to their child's health, not all parents remembered this and some had not expected that the changes would be accompanied by discomfort. The changes caused parents to question whether, by participating in the trial and thus introducing foods early, they were causing their child to suffer. Despite having concerns about whether trial participation was harming their child, only one mother discussed her worries with trial staff. The others chose not to because they thought that they might be viewed as overanxious.

I wondered whether there was any commonality between the parents who considered withdrawing their children from EAT due to concerns about harm, hypothesising that perhaps they had been nervous about trial participation or had a preference for their child to be randomised to the control arm. This was not the case. Even parents who had previous experience of research, who had been very positive about their child's potential participation, who had wanted their child to be in the intervention arm and/or thought they would have weaned their children earlier than the guidance recommended if they had not been participating in EAT, described questioning whether they should withdraw if they thought their child was suffering.

⁵⁵ For example children experienced worsening of eczema, less frequent bowel movements or more frequent or forceful vomiting than prior to study participation.

Sophie's story was fairly typical of the experiences of two other parents, all of whom were first time mothers. She told me at the beginning of the interview how keen she had been to enrol her son in EAT. She viewed research as an essential way to progress knowledge, considered the trial question to be important and thought that the activities she would be required to carry out offered little potential to harm her son. She explained that after she started weaning her son he appeared to be suffering ill health. As she had no prior experience of weaning a child she attributed the negative symptoms to trial participation, although she later amended her view because:

I've now read, or someone told me, that when you start to wean them they start to poo a lot more, which I didn't know, and so I thought he had diarrhoea [...] so I think perhaps I over reacted slightly, but I guess because you, because I was doing the study I was thinking, oh my god, what have I done to my baby? I've given him diarrhoea. But I'm a first time mum so I worry about these things more. [Sophie, E53MI]

Sophie went on to say that, after her initial unease, she rationalised that even if she was not participating in EAT she would have to give her son solid food in the near future. She recognised that these symptoms may occur at that time and thus ultimately decided that trial participation may not be directly responsible for the discomfort her son was experiencing.

The other three mothers who thought about withdrawing had older children and so were familiar with weaning a baby but found the process of weaning the child who was participating in EAT more negative than that of their older children, even though they had also been weaned at a similar age to the trial child and earlier than the recommended six months of age. For two parents, the problems resolved quickly and as their concerns about participation were short-lived their thoughts of withdrawing soon dissipated.

Despite seeking advice from trial staff, Isla's daughter's symptoms did persist and, after some time, she felt she must withdraw her from the trial:

She was projectile vomiting and I just thought this is ridiculous [...] you just assume babies want to eat, um and she'd been a very contented happily breastfed baby, so why change, why try to force her to do something before she's ready? [...after this realisation] I wrote the letter [of withdrawal] and put it in the post. [Isla, E52MI]

Her decision to withdraw also reflected her concerns that, as her daughter was not adhering to the trial regime, their participation was pointless because their contribution would not help to advance knowledge. Coincidentally the staff contacted her a few hours after she posted the letter to see whether their initial advice had been helpful. Isla told the staff member who phoned her that she had written to withdraw and when the staff member understood the reasons for this she reassured Isla that she should take the weaning process at a pace that she and her daughter were comfortable with. At the end of this discussion Isla decided to remain in the trial. She felt reassured that she could modify her child's participation to a level that was acceptable, that the health of her daughter was more important to the staff than the results of the trial, and that her contribution was worthwhile.

These stories highlight that, although LEAP and EAT were initially viewed by some, including parents who considered withdrawing because of concerns about harm, to be innocuous,⁵⁶ views of the field of medical research as 'risky' appeared to subconsciously linger in the minds of even parents who were overtly pro-research and/or who had

⁵⁶ A government survey showed that 51% of infants (who are not taking part in trials) have been given solid food by 4 months of age (Bolling 2007). Perhaps for this reason many parents and staff considered that the study was 'low risk' because many UK parents were already conducting the trial interventions as part of their daily lives.

considered the trials to be low risk prior to enrolment. They also further highlight the magnitude of the power that the field of parenting had over the trials' fields. Parents considered that they must protect their children from harm and during participation some questioned whether they were neglecting this duty. This concern was amplified because their child could not contribute to the decision and parents thus thought hard whether, by continuing participation when their son or daughter appeared to be suffering, they were imposing their values on them. In such instances their parenting role took precedence over the importance they placed on contributing to society; being a 'good parent' was of greater importance than being a 'good citizen'. If they could not reconcile protecting their child with their perceived duty to be a good citizen then they thought about withdrawing their children from the trials. Isla's story highlights how the staff were often able to assist parents with reconciling their two roles.

It was evident in all the data that staff from both LEAP and EAT strove to minimise harm to children. This meant that they sometimes deviated from the protocol by, for example, not taking blood from children, or not conducting protocol defined food challenges. The motivations for these deviations appeared to relate both to minimising harm for the participating children and to maintaining parental trust in the trial staff, as this excerpt from my field notes illustrates. In this episode the little boy's skin testing was within a range that meant that, according to the protocol, he would undergo a food challenge to see whether he was allergic to the trial food:

Michelle looked at the skin test results and said to the mother that they would probably do a food challenge but that Hugh would decide. Hugh saw the skin test and immediately told the mother that they would not do a food challenge as her son was likely to have an allergic reaction. Michelle did not hear this conversation and later asked Hugh why they

were not doing a food challenge. He said that the child was very likely to react and, whilst looking at the mother for verification, he thought the mother would prefer not to. The mother smiled and said she would rather not. [Field notes, 21st October 2010]

The approach that staff took to minimising the harm caused to children from participation appeared to reflect not only their understanding of their ethical responsibilities, but also their personal values. During my observations it was clear to me that the staff wanted to do their best by the participants, not simply because they must abide by protocols and ethical rules, but because it was important to them to treat the families with care and respect. As illustrated by the modifications that they made to the protocols and to the pragmatic approach they took to facilitating intervention adherence, for them, ensuring the safety and well being of the participating children was more important than achieving a 'perfect' trial outcome if the two were not compatible.

These values were noted by many parents. Rebecca, who had recently enrolled her son in EAT told me about a phone call that she received during which one of the staff told her that her son needed to have a repeat blood test because his initial test revealed a low white cell count:

One of the staff phoned and said I've had this conversation five or six times. It's really nothing to worry about, babies' white blood cells fluctuate, but we have to dot the i's and cross the t's before we start. And that reassured me even further, that he wasn't saying well this isn't quite right but we'll get started anyway [...] that gave me confidence that they are being very careful about everything being correct before they start. [Rebecca, E40MI]

Understanding that staff placed the interests of participating children over the interests of the trials' outcomes, and thus that the values possessed by staff and their aims were

comparable with the parents' own promoted parental trust in LEAP and EAT staff. This was particularly important for parents who considered withdrawing their children due to concerns about harm. Coming to understand that they and the staff each wanted the best for the children often provided the reassurance that was necessary for their continuing participation.

Although staff strove to minimise harm for the participating children they could not achieve this all of the time. One element of participation that they had no control over was whether the children developed food allergy during the course of their participation.

8.4.1 Becoming allergic to a trial food during participation

The aim of both trials was to uncover the best way to prevent children from developing food allergies, but some children did become allergic during the course of their participation. The parents of four children who became allergic took part in the interviews for this study. One child was in the control arm and three of the children were in the intervention arms of the trials. One of these families chose to withdraw their child because of concerns about harm and Lesley's experience is described in Box 3.

Lesley: E34MIW

Lesley and her husband had two daughters, the youngest of whom they enrolled in EAT. Lesley took part in the interview and described having limited knowledge and no previous experience of research. Despite this, she was positively disposed towards research and thought both that research in general was *'very worthwhile'* and that EAT was *'really interesting'*.

She heard about EAT through a flyer that was sent to her home address just after she had her second daughter. She had no family history of allergies and she had not been concerned that either of her daughters would have allergies. Her motivations for participating reflected her interest in the question that EAT hoped to answer and her attitude, underpinned by her Christian values, that it was *'important to help out where possible'*. She also explained that EAT's eligibility criteria contributed to her decision to take part. Only children who had been exclusively breastfed prior to recruitment could be enrolled and she recognised that this would limit the pool of potential participants. As her family fell within this exclusive group she felt that she had a duty to participate if at all possible.

Prior to attending the first visit she spent some time establishing whether the trial was *'kosher'* or *'dodgy'*, mentioning her potential participation to her health visitor who considered the trial to be interesting. She told me that her husband also saw the relevance of the trial question and, similarly to her, felt that their participation would help others.

Lesley considered that the first trial visit was a positive experience; she felt welcomed and understood what would happen. Her daughter was randomised to the intervention arm of the trial and the first few weeks went well. She felt that her daughter was ready to be weaned and, although she had originally hoped that she would be randomised to the control arm, was pleased to be able to introduce solid food.

Although her daughter struggled to consume the correct quantities of some foods Lesley was reassured by the staff saying that she should go at her daughter's pace. She had no concerns about participation until, a few weeks after enrolment, whilst feeding her daughter tahini (sesame paste) at breakfast, she noticed that she had a rash. This rash quickly spread over her face, she began to vomit and Lesley realised that her daughter was having an allergic reaction. After phoning her local GP who was unable to offer an appointment she contacted the trial staff who recommended that she give her some antihistamine and take her to the local accident and emergency department if the GP was unable to see her. Although her daughter recovered well, Lesley described the experience both as frightening and embarrassing.

They classed it as a mild reaction, I would hate to see what a more serious reaction would be, must be really ultra scary.

So we took her to the hospital [...] we went to the children's bit of that, and yeah, and it's just, you know, it's a little bit embarrassing, saying why she's like that, because she's having tahini. And I was

like, I know you don't normally give babies tahini [...] but I was trying to explain that I was doing this EAT study.

The EAT investigators contacted her the next day to see how her daughter was. As she had previously eaten sesame without allergic symptoms, Lesley was invited to take her daughter for a trial visit to establish definitively whether she was allergic to sesame. She attended this visit about a month after the reaction and in the interim decided not to give her daughter either sesame or peanut, being concerned that she may experience similar symptoms. At the trial visit her daughter underwent a sesame food challenge and suffered another allergic reaction during which she was very sick. As she vomited for some time she had to remain in hospital under observation until the early evening. They lived some distance from London and consequently arrived home after 10pm. After this experience the mother told me that her husband decided that they must withdraw from the trial.

He was annoyed, like if she wasn't doing the study this [the first allergic reaction] wouldn't have happened type thing [...] and then the fact that she had the other reaction, so you know, we're making her, or they're making her ill again, sort of thing, and back late on our own, so he was like fuming basically. So um, and that's the reason why we're not doing it anymore.

When the trial staff contacted her the next day to see how her daughter was, her husband told them that he was withdrawing his daughter because trial participation had placed her at serious risk and caused her to suffer. During this conversation her husband became very angry and Lesley explained that she '*felt bad for the doctor [who talked to her husband] because it's not his fault*'. She emailed to apologise for her husband's manner and to explain that although she considered it a '*brilliant study to do*' they did not want to risk their daughter's health with further participation. The trial investigator responded with an invitation for them to attend for a review after a year had elapsed, but Lesley chose not to accept the offer or mention it to her husband because she thought he would be angry that she had had further contact with the trial staff.

She explained that, despite this experience she still felt positively towards research, although she thought her husband probably had different views. She said that they would only consider future participation in research if there were no risk to their children such as studies requiring only height and weight measurement.

Box 3: Lesley, who withdrew her daughter from EAT

The circumstances that led Lesley and her husband to withdraw their daughter from EAT were very similar to those of Janine, whose daughter became allergic during participation in LEAP but who decided to remain within the trial. Janine's little girl also suffered an

allergic reaction (to peanut) both at home and again on the clinical trials unit when, as there was significant doubt as to whether she was allergic, she also underwent a food challenge. I asked Janine whether she had, at any time, considered withdrawing from the trial or regretted taking part, but she said that she had not:

HF: Did you, did you regret your decision to put her in?

Janine: No, no never [...] she had a horrible reaction [...] I was quite worried and at that moment I felt a little bit guilty, but I always felt that it was for her own good.

[later in the interview]

HF: Have there been any times where you've thought about withdrawing from the trial?

Janine: No, not at all, never. [Janine, L29MI]

Several differences existed between these families that may help to account for their differing decisions about continuing participation. Janine, who chose to stay in the trial, explained that her daughter had so many other food allergies that she had almost anticipated that she would be peanut allergic. The diagnosis was not particularly surprising and she had seen her daughter experience similar allergic reactions to other foods prior to enrolling in the trial. She appeared to adopt a philosophical outlook regarding the role of trial participation in her child's allergic status, considering that she may have experienced reactions or become allergic to peanut anyway.⁵⁷ However, Lesley said that, although she had known that her daughter could become allergic during the course of participation, she *'tended to think positively'* [Lesley E34MIW] and assumed that it would be unlikely to happen. Moreover Janine said that her husband shared similar

⁵⁷ Parents of the other two children who became allergic during trial participation adopted a similar outlook, considering that their child may have become allergic even if they had not participated in the trials.

views to her and, as she was a doctor, he had been happy to leave the decisions about participation to her, whilst Lesley told me that her husband was particularly cross that they had allowed their child to suffer. When their daughter became allergic he felt that they had failed in their parenting duties to protect her and when she suffered the second allergic reaction on the clinical trials unit he decided that they must withdraw to prevent such an instance from occurring again.

Although I did not ask the EAT staff specifically about the circumstances of Lesley and her husband withdrawing their daughter from the trial, when I asked them to talk generally about the families who had withdrawn one of the staff talked about this family. Anton had been the member of staff who had spoken to Lesley's husband when he had said that he wanted to withdraw. Anton said he had told the father that, regardless of their ongoing participation the trial team would offer as much support as they could to help the family to manage their daughter's sesame allergy but that he had refused this and had also discussed taking legal action. Anton told me that at this point he had, *'gently explained that his wife had signed a consent form'* [Anton, Staff 10] agreeing to his daughter's participation, and that part of the written information attached to this consent form had explained that it was possible that children may become allergic during the course of their participation.

Although Lesley told me that her husband had been aware of their participation, during the course of their conversation Anton felt that the father had not been aware that his daughter was taking part in a trial. Regardless of whether Lesley's husband knew that his daughter was taking part in research it was clear that his view that participation had caused his daughter harm resulted in him withdrawing her from the trial. It was also apparent that, unlike Janine and many other parents, he did not consider that the trial

staff had the best interests of his daughter at heart. He felt that they had allowed her to suffer unnecessarily, and his perception that the trial staff's values were different to his own also seems to have contributed to his decision to withdraw her from the trial.

In the earlier part of this chapter I highlighted the importance of benefit, reciprocity and harm to retention in LEAP and EAT. As was the case for recruitment and adherence, the manageability of participation was also relevant.

8.5 Manageability

The ability to manage the activities that participation required was an important aspect of trial retention. Staff on both trials told me that they had assumed that manageability would be important and strove to reduce the burden of participation in a variety of ways. During protocol development they had tried to keep the number and duration of study visits to a minimum and LEAP also incorporated home visits into their protocol to reduce inconvenience to parents. As well as being flexible with the timings of visits and trying to conduct the visits efficiently, as I described earlier, staff were also alert to the individual circumstances of parents who were finding participation too onerous and tried to reduce the burden of participation where possible. These efforts were predominantly successful, and parents said that their ability to easily adopt trial activities into their lives had a positive influence on retention, a finding similar to that reported by Roder et al. (2008). When I asked parents why they had not considered withdrawing from the trial many replied that participation had not been difficult:

The food diaries are quick and painless really, and the visits, you know they feel like such a long time ago now, that yeah, they were, you know, quite quick and easy [...] so yeah it doesn't feel particularly onerous.

[Michaela, L25MI]

Although staff devoted considerable time and effort to ensuring the duration and number of visits were manageable it seemed that less thought was devoted to the manageability of the intervention, including whether small babies could consume the required quantities of foods. During the interviews both parents and staff told me that, for some babies, the quantities were not manageable. This view was particularly expressed by EAT staff and parents and the lack of a pilot phase for EAT was lamented by some staff, who considered that babies' inability to consume the correct quantity of the trial foods had a negative influence on parents' perception of the trial and, therefore, on retention.

For parents whose children struggled to consume the correct quantities of foods, trial participation was not easy. During our discussions about the issues they considered when deciding whether or not to take part, parents told me that they had thought about whether participation would be manageable, considering aspects such as the number of visits or frequency of questionnaires. Parents also told me that they had thought about the practicalities of the day-to-day activities of participation. As these essentially involved feeding children specific foods, most of which were part of the families' usual diet, they felt that participation would be no more arduous than if they were not taking part in a trial; they would be weaning their children anyway. This assumption was perhaps reinforced by the information sheets provided to parents at the beginning of the trial. These clearly stated the likely time that would be required for activities such as questionnaire completion and trial visits, but, beyond stressing the importance of giving or avoiding the foods, made no mention of the time required for carrying out the intervention. As the trial intervention required only that parents avoid or give their children foods as part of a usual meal this is perhaps unsurprising. However, over the

duration of the trial, preparing the trial foods and giving them to the children was actually the greatest time commitment for parents.

When talking about their experiences after enrolment it was evident that the realities of participation did not always meet parents' expectations. They told me that giving their child the correct foods, in the correct quantities, at the correct frequencies, was more effort than if they had not been taking part. As Xanthe, whose son would not consume the correct amount of peanut, explained, this made trial participation time consuming and stressful, and for a time she questioned whether they could keep taking part.

To start with he didn't, he didn't like [the peanut], it could take hours sometimes, to get it in [...] it was three times a week, and you'd think, oh no it's today, oh god, I've got to do it again, so, so yes it was quite stressful actually, just feeling 'oh are we going to be able to carry on with it' [trial participation]. [Xanthe, L17MI]

Like other parents, her persistence with participation reflected her habitus, her core belief that it is important to complete activities that you have agreed to participate in.

Xanthe: I'm just not the sort of person that withdraws from anything actually [...] if I take something on I tend to stick with it and if I [don't], it feels like a bit of a failure.

HF: And that kind of see it through attitude, where does that come from?

Xanthe: Oh I think probably from my mum [...] if you sign and say you're going to do something you don't pull out of it, er, so I think it's just, just the way I'm made really.

[Xanthe, L17MI]

After a few weeks, her son ate the peanut snack more readily and she felt able to continue with participation. However, parents for whom the situation did not improve told me that they began to have negative feelings about their participation:

I ended up making, like breast milk custard for her [...] and obviously then it started getting quite hard work [...] yeah and just finding it soul destroying as well that she wasn't taking it [...] so for me it was sort of creating a stress around mealtimes that I didn't feel should be there.

[Vicky, E51MIW]

As I described earlier, once staff became aware of these difficulties they 'personalised' the protocol to improve the manageability of participation according to the needs of the individual family. Yet, as I described in Chapter 7, parents were not always willing to admit that they were struggling with participation, considering that they would be viewed as 'bad parents' because they would appear not to have thought about participation sufficiently prior to consenting to their child's enrolment in the trials. The ability of staff to detect these problems and offer solutions was often dependent on frequency of contact and the relationship they had developed with the parents. As I argued in Section 8.2.3, the design of the trials meant that this was more easily executed in LEAP than in EAT.

8.5.1 Changes to circumstances and manageability

Managing the burdens of participation naturally changed during the course of these longitudinal trials. During the interviews parents and staff told me that changes to life circumstances had the potential to influence retention.

In some cases changes to the environment were relevant to retention. For example Mercy, whose son had been participating in LEAP for about three years, explained that as peanuts were a substantial part of her family's usual diet for the majority of their

participation avoiding them had been inconvenient but manageable. However, her son was about to start pre-school and when she told the school staff that he was not allowed to eat peanuts they said that this would mean that he could not have school meals as they could not guarantee they would be nut free. Mercy said that she and the LEAP staff were engaged in discussions with the school to establish whether the meals contained substantial quantities of peanut and to clarify that trace amounts of nuts were acceptable but peanut containing foods were not. At the time of our interview these discussions were still ongoing, but she told me that, if his participation meant that he could not receive school meals, then she might have to withdraw from the trial:

So now the school is saying, if he's going to avoid peanuts he'll have to skip, has to skip the dinners and everything, so that's going to be an issue and I think I would have to decide now whether I want to do [the trial] for the last year.

[Mercy, L22MC]

Given the longitudinal nature of the trials, changes to the life circumstances of participating families were inevitable. Parents seemed remarkably resilient to these changes and managed to continue participation even in very difficult circumstances. During the interviews several of the LEAP staff described the dedication of two families for whom the father of the trial child had been diagnosed with cancer (in one case the father died) but who continued participating in the trial. The trial staff chose not to allow me to invite these parents to take part in the study and so I could not ascertain why they continued to participate in such difficult circumstances. However, I would hypothesise that their ability and willingness to continue with their children's participation reflected the relationship that they had built up with the LEAP staff.

It was predominantly EAT staff who told me that changes to life circumstances meant that parents chose to withdraw their children from the trials. When staff learnt of these

situations they would offer to support parents to continue with their participation if they wished to by personalising the protocol to meet their needs. However, the low level of personal contact that was scheduled in the protocol meant that staff often only became aware of problems after parents had struggled for some time, by which point the offer of support was too late. This is evident in the experience of Vicky, who withdrew her daughter from EAT when life circumstances made participation unmanageable. Her story is summarised in Box 4.

Vicky: E51MIW

Vicky and her husband were approached to participate in EAT by a researcher when they attended an antenatal appointment prior to the birth of their second child. Vicky, who took part in the interview, had a good knowledge of medical research, having worked on various medical trials as a research assistant during her career. She was positively disposed to research and had been interested in the research question, having wondered herself whether the advice she had been given regarding what to eat during pregnancy and how to wean her first child was correct:

I hadn't been convinced by some of the guidelines I had been asked to follow [...] second time around I just sort of followed a bit more, you know, what my body wanted to do.

Vicky agreed to participate in EAT when she was midway through her pregnancy with her second child, although she and her husband did have some concerns about whether the new baby would 'take to breastfeeding' as she had had problems breastfeeding her older daughter. She was also a little worried about weaning the new baby, as her older daughter had 'never really had a big appetite'. Despite these concerns, her interest in the trial question and the potential to have her daughter allergy tested made participation appealing. She and her husband made the decision between them, although she told me that her husband had some reservations:

He was quite interested but he's a bit more practical than me. So I can get carried away with the idea of something, get really enthusiastic about it, but he can be a little bit more cynical. [He] was happy to take part, but also was quite staunchly, you know, we need to look after ourselves and the study comes second.

Just before her daughter was born, Vicky's mother was suddenly taken ill and died when the baby was two weeks old. At the time she considered that she wanted to continue with her participation, and attended the first trial visit when her daughter

was three months old. She described the visit as being '*a little bit difficult*' as she was still getting used to having two children and had to entertain her older daughter during the visit. She had also forgotten that her daughter would have a blood test, and was a little upset at the thought of it, but did not want to admit this as she thought she would '*look like a really bad mum [...] that I hadn't, um, read everything properly*'. Fortunately the blood taking did not distress her daughter, and she left the unit with no concerns about their continuing participation.

After being randomised to the intervention group her daughter struggled to consume the required quantities of some of the trial foods. Vicky contacted the trial staff who gave her some advice. However, she quickly began to find participation arduous. She felt as if she was wasting her time by failing to give her daughter all of the foods that were required. She also began to get behind on filling in the questionnaires because she was too busy to keep accurate records, and when she came to complete the questionnaires she felt that, as she couldn't complete them accurately, her participation was pointless. Vicky explained that she began to find the study hard work, and, coupled with her grief at the loss of her mother and the pressures of the day-to-day activities that accompany being a mother of two young children, she began to find life extremely stressful.

She explained that she had a discussion with the trial staff during which she described how hard she was finding participation, although she couldn't remember whether she had told the staff that she was also coping with a recent bereavement. Following this discussion she agreed to continue participating by completing the online questionnaires but only feeding her daughter foods in the quantities and frequencies that she considered manageable. I asked if she was happy with this decision and she said that she was '*probably 75% ok with it, but again, another, secretly in my mind thinking, oh have I done the right thing?*'

Unfortunately Vicky continued to find her life stressful, and even completing the questionnaires added to this stress. At this stage she sought medical advice from her GP regarding her health. Following this her husband decided they must withdraw their daughter from the trial:

And I'd been to the doctors and he'd, we'd discussed antidepressants but I couldn't have any because [my daughter] wouldn't come off the breast, um, and yeah I think when I got to that stage I just start thinking about how to reduce the amount of stress, anything that you can do without that's stressing you but [my husband] said right, that [trial participation], that's not an essential part of my life, so, so that has to go.

Despite having to withdraw she said that her views of research had not changed since her participation in EAT, and she would consider future research participation for her children.

It was evident from Vicky's interview that trial participation became one burden too many. Although the staff tried to tailor the protocol to her needs, she found that the additional activities that she was required to conduct compounded other problems she was having. She tried to continue but was frustrated that her contribution was not useful and when her health began to suffer her husband decided that any activities that were not essential to their daily lives should be ceased to try and reduce the pressure she was under. It is impossible to know definitively, but had she been in more frequent contact with the trial staff they may have been able to offer her regular reassurance that the level of participation she was achieving was satisfactory. This may have reduced some of the stress she felt about her daughter's participation in the trial and allowed her to feel able to continue taking part.

8.6 Conclusion

Unlike recruitment and, to some degree adherence, retention to LEAP and EAT was influenced more by the conditions of the trials' fields, than by the interrelationship that existed with the wider fields. This was particularly evident when comparing the retention rates between the two trials.

The availability of economic capital was clearly important for retention. In LEAP, the resources allowed and the trial design required that staff make frequent contact with parents. This contact created the conditions by which social capital is acquired (Bourdieu, 1986) allowing the development of relationships from which parents accessed expertise that helped them to care for their children and staff accessed the data that were needed. The desirability of these relationships was enhanced by the lack of expertise in the field of allergy healthcare and by the philosophy of the parenting field, in which parents strove to do their best for their children.

The relationships that developed were also enhanced when they reflected an understanding that both the parents and the trial staff had the best interests of the participating children at heart. Regardless of the trial that their children were participating in, there were several instances in which parents chose not to withdraw their children because conversations with staff allowed them to understand that their goals for participation were similar.

The importance of this relationship for retention is made explicit by its absence in the instances of the three families who withdrew their children from the trials. Brigitte did not consider that she had a good relationship with LEAP staff and Lesley and Vicky's husbands, who had limited contact with the trial staff, made the final decision that they should withdraw their children from EAT. It could be argued that Lesley and Vicky told me that their husbands had made the final decision because they felt guilty at that they had withdrawn, but I think this is unlikely. Anton, one of the EAT staff spontaneously told me he thought it was Lesley's husband who had made the decision to withdraw.

Furthermore, rates of attrition were higher in EAT, which had proportionately fewer resources and more limited personal contact between parents and staff than LEAP. That LEAP parents considered that the phone calls contributed to their continuing participation also lends weight to my argument.

Whilst retention to LEAP and EAT was influenced by the conditions of the trials' own fields, the notion of social cohesion posited by Titmuss (1970) was also important.

Parents continued to take part in the trials because they felt that it was only by doing so that the trials would produce outcomes that would advance knowledge about food allergy. This desire to contribute to society was complemented by parental perceptions that it was important to complete the activities they had agreed to and it seems that both

were the result of their habitus; their previous experiences and personal values meant that they were disposed to behave in this way. These values also included a belief that give and take were important, and this reciprocity reflected not only a need to give back to society, but also to give back to the trial for the care that they had received for their children. Furthermore, the staff also valued reciprocity believing that it was important to repay the contribution that parents made by providing care that went beyond the immediate boundaries of the trial protocol.

All of these ideas are explored further in the final chapter, the discussion.

Chapter 9: Discussion

The aim of this thesis was to further understanding of participation in non-therapeutic paediatric RCTs, such as those that investigate interventions to prevent disease development, with a view to acquiring knowledge that would help those who plan, fund and conduct trials to achieve robust outcomes and thus make the best use of the available resources.

To date, the majority of studies considering participation in paediatric RCTs have focused on recruitment to therapeutic trials, particularly trials in the specialities of oncology or neonatology (see for example Deatrick et al. 2002; Snowdon et al. 2007; Ward 2009; Woodgate and Yanofsky 2010). The circumstances under which parents are invited to enrol their children in trials within these specialities, often soon after receiving news that their child has a life threatening condition, reduces the applicability of the findings to the wider sphere of paediatrics. A small body of work has considered recruitment to therapeutic trials in other specialities (see for example Glogowska et al. 2001; Pletsch and Stevens 2001a; Shilling et al. 2011). The findings of these studies are perhaps more relevant to non-therapeutic trials, but certain key differences still exist. In therapeutic trials the children have an underlying health condition, the trials involve the testing of medications and parents are usually approached to participate in the trials by HCPs who have been involved in the care of their child. These circumstances are different to those experienced by parents who are invited to enrol their children in non-therapeutic trials.

Whilst there is a growing body of work investigating recruitment, few studies have considered adherence or retention in paediatric RCTs. Of those that have explored these aspects of participation, most have explored adherence and retention in therapeutic

trials, few have sought the viewpoints of those involved, and none have examined recruitment, adherence and retention within the same trial. This study offers a broader view of participation in paediatric RCTs than has been adopted in the majority of studies to date since it: considers research participation in non-therapeutic trials; explores and compares the views of parents and staff; examines contextual issues; focuses on adherence and retention as well as recruitment; and considers the interaction between all three aspects of participation. The findings may be of practical use to those who plan and conduct RCTs. They also add to the existing theoretical debates regarding the relative merits of societal benefit and personal benefit models of participation in prosocial healthcare activities.

In this final chapter I discuss the key findings and their practical implications, consider the limitations of the study and discuss areas for future research. In doing so I draw, as in previous chapters, upon Bourdieu's (1977; 1990) Theory of Practice. To my knowledge this is the first study to have used Bourdieu's theory to explore trial participation, and I found it useful in promoting a depth and breadth of investigation that might not have been possible had I chosen a more 'specific' theory, such as a theory of risk. However, whilst Bourdieu's theory was helpful in exploring conceptual aspects of practice, it did not promote understanding of more practical matters, such as whether an individual has time or is physically able to practice in a particular way.

In applying the theory to this thesis it was also evident that, by proposing that an individual's practice is dependent upon accruing and exchanging capital which is achieved by competing with others, Bourdieu overlooks a whole facet of practice: individuals may act not in competition with each other, but alongside each other. Titmuss' (1970) *The Gift*

Relationship was used to help overcome this limitation, and to my knowledge it is the first time that the two theories have been used together to explore health related practices.

9.1 Key findings

In investigating recruitment, adherence and retention in LEAP and EAT it was evident that, although each individual aspect had its own unique requirements and challenges, there were areas of commonality between all three. In this section I discuss the significance of context and the relevance of societal and personal benefit models of participation for recruitment, adherence and retention in LEAP and EAT.

9.1.1 The significance of context for recruitment, adherence and retention

Bourdieu (1990) argued that practice is influenced by the resources (capital) and values and dispositions (habitus) of actors within a specific area of social activity (field), and by interactions between fields. He considered that an individual's habitus and the capital they possess within a specific field determines the extent to which capital may be exchanged between fields. Thus fields that possess substantial capital will be more successful than those with fewer resources and consequently will have a greater influence over practice.

Previous studies exploring participation in paediatric trials have predominantly focused on the sociodemographic characteristics of parents or the views and practices of parents and staff within the context of the trials. Such approaches neglect the possibility that trial participation is influenced by the wider social context. The findings of this study suggest that the wider context within which the trials were taking place had a substantial influence on recruitment, and, to a lesser degree, adherence and retention. The practices of LEAP and EAT parents and staff were undoubtedly influenced by the interaction that took place between the trials' fields and the wider fields of medical research, infant

feeding, healthcare, and parenting. As I go on to discuss, the capital that was available to those who practised within each field and the degree to which the fields' collective habitus converged was relevant to recruitment, adherence and retention in LEAP and EAT.

In the following sections I discuss the interaction that took place between the trials and three of these fields: medical research, infant feeding and healthcare. I then highlight the centrality of the parenting field for trial related practices and discuss how its relationship with each of the other fields influenced recruitment, adherence and retention in LEAP and EAT.

9.1.1.1 Medical research and the trials

It was evident that recruitment, adherence and retention in LEAP and EAT were influenced by the history of the field of medical research. In 2004 the UK government identified '*deep public concern*' (HM Treasury 2004 p.103) over the way that science is regulated and used, and the findings of this study show that such views persist. Online discussion forum data revealed that some members of society do not take part in research due to concerns that they, or those for whom they provide consent, will be exploited or subject to potentially harmful experimentation. Although the data are limited, there was evidence of a lack of trust in research and researchers, a notion that others have also found to be important in research relationships (see for example Helgesson et al. 2009; Thornton 2009).

Combining the online discussion forum data with interview data helped to explain why, as Chantler et al. (2007) also found in their vaccine study, a substantial number of parents who took part in this study and, therefore, in LEAP and EAT, had scientific or medical backgrounds. Their backgrounds predisposed parents to take part by providing parents

with a knowledge and understanding of research that facilitated their assessment of the trials and thus their decision making regarding whether to enrol their children in the trials. In this assessment parents considered the potential for their or other children to benefit and, given the history of the field of medical research, the trustworthiness of the funders and staff who worked on these specific trials.

Many studies have shown that parental perceptions of risk are important for recruitment (see for example Pletsch and Stevens 2001b; Deatrick et al. 2002; Dunngalvin et al. 2009), and the findings of this study reveal that these views, at least in part, reflect the perceptions of the history of the field of medical research. They also suggest that both perceptions of risk and negative views of medical research continue to exert an influence on participation after recruitment. Parents whose children experienced ill health soon after being enrolled assumed that it was the trial activities rather than the natural infant weaning process that was responsible. This suggests that views that research is 'risky' were held, albeit subconsciously, by even the most overtly pro-research parents and those who had felt comfortable with the risks of the trial prior to recruitment.

Regardless of their previous knowledge and experience of research, many parents held views of the 'rules of the field' (Bourdieu 1992) of medical research that had the potential to positively influence adherence and retention. They saw medical research as rigorous and precise and believed that the trials' outcomes relied upon their diligent and continuing participation and upon providing honest and accurate information to the trial staff. However, when participation was not easy their perception of these rules, coupled with a predisposition to complete activities to the best of their ability, led parents to find participation so stressful they considered withdrawing. Yet the 'rules' of LEAP and EAT's fields were different to those with which parents were familiar. Parents assumed that

these trials fell within the internally valid 'explanatory' paradigm of research with which they were accustomed. However, these trials fell within the 'pragmatic' sphere, where internal and external validity are balanced so as to maximise the practical utility of the findings (Godwin et al. 2003; Treweek and Zwarenstein 2009). For this reason, within LEAP and EAT, reduced levels of adherence were acceptable and staff viewed retaining participants and achieving good levels of follow up adherence as more important than stringent intervention adherence if these were not compatible. When parents came to understand these differing 'rules,' intervention adherence was reduced but trial retention was enhanced.

9.1.1.2 Infant feeding and the trials

The philosophy of the field of infant feeding was that allergenic foods should be excluded from infants' diets. The philosophy of the trials, reflected in their hypotheses, was that it might be more beneficial for infants to be introduced to allergenic foods at an early age. Thus the collective habitus of the two fields (infant feeding and the trials) were divergent. This divergence was relevant to recruitment because it influenced parental and HCP collaborators' perceptions of equipoise and thus their willingness to accept randomisation.

Other have also described the importance of equipoise for recruitment (Mills et al. 2003; Garcia et al. 2004; Snowdon et al. 2007; Ziebland et al. 2007) but, to date, no study appears to have explored how views of equipoise vary between groups of HCPs, or between HCPs and the public. The findings of this study suggest that equipoise was influenced by the degree of convergence between philosophies of the trials and those of the wider fields, and by the resources, or capital, available within each field. Differences in the collective habitus of the field of infant feeding and the hypotheses of the trials,

combined with disparity in the capital available to those acting within each field, meant that those acting within the field of infant feeding exerted a substantially more powerful influence over the views of parents and HCP collaborators than those acting within the field of the trials. For this reason many parents and HCP did not consider there was uncertainty regarding the best way to prevent children from developing food allergy. Rather they favoured the practice that formed the control arm of the trial and that was promoted by the influential organisations and professionals acting within the field of infant feeding.

The field of infant feeding also exerted an influence on adherence. The practice of ensuring that young children avoided allergenic foods such as peanuts, coupled with concerns about the protection of children with food allergies, meant that many nurseries and schools had 'nut free' policies. Although this created favourable conditions for adherence for children in the control arms of the trials, the opposite was true for those randomised to the intervention arms. Because children were unable to consume peanut containing foods at nursery or school, their intervention adherence was sometimes reduced.

9.1.1.3 Allergy healthcare and the trials

The dearth of specialist allergy services within the field of healthcare was relevant for all aspects of participation in the trials, but was particularly influential for recruitment to LEAP, which only enrolled infants with eczema or egg allergy. HCPs who worked for the trials possessed allergy specific knowledge that parents wished to draw upon; in Bourdieu's (1986) terms, the knowledge staff possessed was a source of social capital for the parents because trial participation offered them access to a valuable resource: the expertise they needed to care for their child. As others have also found (see for example

Deatrick et al. 2002; Fairhead et al. 2006; Sammons et al. 2007), the potential to access healthcare that was not easily available outside the trial had a positive influence on recruitment. That LEAP and, latterly, EAT staff described this service in their marketing materials reflects that staff understood that, whilst children's participation provided valuable data for them, it was also a valuable resource for parents. The mutually beneficial nature of the trials also facilitated trial retention. As others have found (Janus and Goldberg 1997; Geromanos et al. 2004; Dias et al. 2005) parents continued to take part in the trials so that they could access the care that they wanted for their child.

9.1.1.4 The interrelationship between parenting, the trials, healthcare, medical research and infant feeding

Although the fields of medical research, infant feeding and healthcare were all relevant to participation in the trials, it was the way that the philosophies and values of the individuals within each field interrelated with those within the field of parenting that seems to have exerted the greatest influence on recruitment, adherence and retention.

Several authors have argued that the underlying philosophy of the field of parenting reflects a societal view that it is essential to protect children from the risk of harm (see for example Lee et al. 2010; Wolf 2011; Gillies 2012). There was certainly evidence of this view in the data. The decisions that parents made regarding their children's initial and continuing participation were discussed in terms of doing their best by their children. This finding is likely to reflect not only parents' personal values, but also the considerable professional intervention and monitoring that occurs within the field (Lee et al. 2010). In doing their best by their children parents acquired prestige, or symbolic capital, from those who judged their parenting abilities.

It was not only parents who described putting children's needs first. The staff also justified their decisions about participation in terms of acting in the participating children's best interests. As I discuss in the following section, this concordance of philosophy was relevant for recruitment, adherence and retention in LEAP and EAT.

9.1.2 Doing their best by children: concordance in the views of parents and staff

The extent to which parents felt that the staff would put the needs of their children first was important for all aspects of participation. As the majority of parents had no previous relationship with the staff before they heard about LEAP or EAT, it was in their first interaction with the staff that parents could assess this. Their views were influenced by their prior experiences and beliefs about research and researchers in general, as well as the interactions they had with the staff. As I discussed in Chapter 6, parents considered that 'research' was a diverse field. Whilst most viewed LEAP and EAT as low risk in terms of the potential for harm, they felt that designs that were more 'experimental' were undesirable, a finding similar to that described by Cico et al. (2011) in their study of the influence of informed consent language on hypothetical research participation.

Once enrolled on the trial, if parents felt that participation was causing their child to suffer they had a low threshold for discontinuing either aspects of or all of their participation. This was particularly the case at the start of the trial and seemed to reflect their concerns about the experimental nature of the research field and the importance they placed on putting the needs of their children first.

It was under such circumstances that the concordance between parent and staff philosophies regarding the protection of the participating children and, perhaps more importantly, parental understanding of this concordance was so critical. Although parents hoped that the staff would put the needs of the individual children first, they did not

assume this would be the case and were pleased when their concerns that participation was causing their child harm were taken seriously. If parents voiced such concerns staff negotiated aspects of the protocol and agreed upon a level of participation that provided useful data for the trial but allowed parents to do their best for their children.

Parental understanding that the staff did not want to cause the participating children any harm or distress facilitated the development of a relationship that was built on mutual trust and understanding. This relationship had an important influence on adherence and retention and was clearly facilitated by the frequent phone calls, and thus frequent personal contact, that was integral to the LEAP protocol. The importance of the relationship is made clear when examining data from parents who withdrew their children from the trials. Brigitte did not feel that she had a good relationship with the staff. Lesley and Vicky both told me that their husbands, neither of whom had had much, if any, contact with the staff, made the final decision to withdraw their children from EAT, and Lesley's husband clearly felt that the staff had not put his daughter's interests first.

Whilst the concordance of views promoted trust within the staff-parent relationship and thus adherence and retention to the trials, another aspect of the relationship was also important for participation: the potential for parents and children to derive benefit. I will discuss this further in the following section, when I explore the relevance of personal benefit and societal benefit models of participation in LEAP and EAT.

9.1.3 The relevance of personal and societal benefit models of participation

In Chapter 2 I reviewed the theoretical literature examining participation in prosocial healthcare activities and highlighted that discussions in this regard could be categorised according to one of two models: personal benefit and social benefit. When considering research participation specifically, the majority of the debates in which the relative

superiority of societal benefit and personal benefit models of participation are discussed have focused on trial recruitment (see for example Harris and Holm 2003; Forsberg et al. 2009). However it is evident that, at least in the context of LEAP and EAT, these questions are also relevant to adherence and retention.

That both societal benefit and personal benefit were important to recruitment is not unique to this study. Others report similar findings (see for example Janus and Goldberg 1997; Pletsch and Stevens 2001b; Chantler et al. 2007; Sammons et al. 2007; Schaffer et al. 2009). Whilst studies have found that personal benefit is important for retention in longitudinal trials (Geromanos et al. 2004; Dias et al. 2005), data from this study provide evidence that, in LEAP and EAT, retention was also influenced by parents' desire to contribute to society. Adherence to the trial protocols, an element of participation that has been under explored, was also dependent upon the opportunity for participating families to benefit and to help others. Parents continued to facilitate their children's participation partly because they wished to prolong the duration over which they could access the expertise held by the staff. However, underpinned by personal values that they should complete the activities they had agreed to, adherence and retention were also dependent upon parental perception that they had entered into a 'contract' with both the staff and with society more generally. This perceived contract led parents to assess whether their participation was making a useful contribution to the trials' goals; those who felt their contribution was not worthwhile considered withdrawing.

As Hallowell et al. (2010) also found, although the theoretical literature suggests that motivations for participation are dichotomously either altruistic or for personal gain, parents often had dual motivations for enrolling their children in the trials and continuing to facilitate their participation. A lack of specialist healthcare had a positive influence on

recruitment and was the prime reason that parents who felt that their child was in need of the expertise that the staff could offer took part. However, it is not true to say that recruitment was only influenced by parental desire to obtain expertise. These parents, and those who had a lesser need for the expertise that participation could afford, also wanted to contribute to society. This view reflected their personal values that it is important to help others in society but the values were not indiscriminate. Rather they were underpinned by Titmuss' (1970) suggestion that participation in prosocial healthcare activities is the result of a sense of belonging and understanding of the need for the trials. Parents who agreed to their child's participation did so because they recognised the practical and emotional challenges faced by parents with food allergic children and the children themselves.

Data gathered for this study build further on Hallowell et al.'s (2010) findings by highlighting that this 'blended' societal-personal benefit model was the result of the emphasis that parents and staff placed on reciprocity. Furthermore, over the course of LEAP and EAT, the priority that parents placed on either approach was variable and changed according to their understanding of the trial activities and, most influentially, the needs of their children.

The theoretical literature suggests that personal benefit models of participation are exploitative (Wendler et al. 2002; Diekema 2005; Wong and Bernstein 2011) and promote a dishonest approach to participation (Titmuss 1970). Yet I could find no evidence of either within the data gathered for this study. Although Lily, Mark, and other parents who agreed to their children's participation in the trials to obtain benefit said that, had they not needed the expertise that the staff could offer they may not have taken part, they did not seem to feel that they had been coerced into participation. Instead they described

weighing up the risks and benefits of participation and felt happy with their decision. That they described their original motivations as 'selfish', and that they continued to take part after their need for the expertise had dissipated despite understanding that they were free to withdraw, perhaps provides further evidence of a lack of coercion.

By contrast, others argue that it is societal benefit models of participation that are exploitative, particularly when those who conduct the research derive substantial benefit whilst those who participate do not (Tutton 2002; Forsberg et al. 2009). Such views were apparent in the data gathered for this study. Parents said that they would not enrol their children in trials if the funders were aiming to gain financially from their participation. This reflected not only their sense of justice, but also the proxy nature of their decision; because they were making participation decisions on behalf of their children, most felt that there should be at least a chance that they could benefit. Moreover, the staff felt that adherence was reduced in aspects of participation that would not benefit the families themselves, particularly if they were unexpected and/or inconvenient for parents.

The findings of this study support the view of Dixon-Woods and Tarrant (2009), who argue that models of research participation are not solely reliant upon the views of the participants. LEAP and EAT staff certainly seemed to play a role in the co-existence of the personal and societal benefit models. Their personal and professional habitus meant that they felt it was right that, as parents and children were contributing to their goals, participation should be beneficial for them. Had they taken a differing view, for example choosing not to provide advice about matters that were not directly related to the trial protocol, the personal benefit model would have been less relevant and thus less evident in discussions regarding adherence and retention. This finding highlights the importance

of considering contextual matters alongside the views and experiences of those who participate in research.

In Chapter 2 I described how national and international guidance regarding children's participation in research infers that personal benefit is desirable whilst cautioning that coercion or inducement is not. I also discussed the difficulties that have been described with regards to ensuring that any incentives participants acquire from participation are not coercive. Whilst this dilemma is often discussed with respect to financial or other tangible benefits, in this study it was the less tangible benefits, such as the expertise that participation affords, that acted as an incentive for parents.

Reflecting their ethical duty to ensure that incentives are not coercive, in LEAP and EAT the 'incentives' of participation, in this case the expertise that staff provided to parents, were bounded. However the boundary was both tacit and flexible and although parental and staff views of the limits of the boundary were generally concordant, this was not universally the case. Brigitte's story highlights the implications of discordance in parent-staff understanding of the boundaries of personal benefit. She did not receive as much help as she believed she should have done and thus felt exploited. This resulted in her withdrawing her daughter from LEAP.

Given these findings it is perhaps time to alter the focus of the personal and societal benefit debate and to consider ways in which trial participation can be underpinned by both models whilst minimising the risk of the sort of misunderstanding that was evident in Brigitte's story, and meeting the goals of those who conduct the trials and the trial participants.

Having summarised the key findings of the thesis, in the following section I discuss the implications of these findings for practice.

9.2 Practical implications of the findings

In conducting this study I aimed for the findings not only to have theoretical relevance but also to be of practical use to those who design, fund and conduct paediatric RCTs.

Five key practical implications are evident in the data: the relative advantages of personal and electronic methods of data collection; the '*ad hoc*' nature of facilitating adherence and retention; the relationship between adherence and retention; the benefits of personal contact for adherence and retention; and the need to consider the influence of the wider social context when designing trials.

9.2.1 *The relative advantages of personal and electronic data collection methods*

The emphasis that is placed on trials providing 'value for money' and the need to use limited resources efficiently means that funders and trialists have a duty to conduct trials in the most cost efficient way (Cooksey 2006; Snowden et al. 2006b). Given the rise of the Internet, using electronic media rather than personal contact as a means of collecting trial data could be viewed as offering many advantages in this regard. Electronic systems are relatively quick and easy to set up, can be automated thereby minimising the risk of missing data due to human error, allow participants to provide trial data at a time and place that is convenient for them, and, importantly, are likely to be less costly than systems which rely on staff to collect data in person. Despite these many advantages, this study has found that electronic systems have at least one fairly substantial disadvantage. The reduced personal contact between staff and parents whose children were participating in EAT limited the opportunity for staff to detect if families were having difficulties with the trial procedures, a situation that, if left unchecked, resulted in

participants feeling they must withdraw from a trial.⁵⁸ It also limited the potential for families who were taking part to benefit from participation through the receipt of expertise and to feel that they were making a useful contribution to an important project, both of which were relevant to adherence and retention in LEAP and EAT. Whilst it is unlikely that many trials will have access to the sort of resources that were available in LEAP, investigators who choose to gather data using methods that do not involve direct contact with participants may wish to consider ways to overcome these disadvantages. In doing so it would be worth noting that participants who experience difficulties completing trial activities will not necessarily contact staff to discuss this, even if encouraged to do so.

9.2.2 *The ad hoc nature of facilitating adherence and retention*

This study also found that, although LEAP and EAT investigators gave some consideration to adherence and retention prior to recruiting participants, the majority of the work of facilitating these aspects of participation was *ad hoc* and involved responding to the needs of the families who were experiencing difficulties. Problems with adherence tended to occur at the beginning of a family's participation in the trial, led some parents to consider withdrawing their children, and often occurred whilst resources were being devoted to recruiting participants. It is thus unsurprising that staff sometimes struggled to meet the needs of these parents. The findings suggest that, when planning the resources that are needed for a trial, those who conduct and fund research should perhaps include a contingency to manage the *ad hoc* requirements of adherence and retention. It may also be necessary to devote additional resources to these activities at the beginning of a trial, when, as participants are learning how to manage the activities that participation

⁵⁸ The same disadvantage also exists in non-electronic systems where personal contact is minimised, such as postal questionnaires.

requires, problems with adherence and retention may be the most likely to occur. This is particularly necessary because staff have less time to devote to adherence and retention activities whilst they are recruiting participants. Creating conditions that facilitate relationship building early in a trial may also help to minimise problems with adherence and retention in the latter phases of longitudinal trials.

9.2.3 The relationship between adherence and retention

Whilst previous studies have considered the sociodemographic characteristics of participating families when trying to explore non-adherence or trial retention (see for example Bender 2002; Bender et al. 2003; Mahrshahi et al. 2008; Williams et al. 2008), the findings of this study suggests that adherence and retention are influenced by context and, furthermore, are related. Rather than assuming that poor adherence is the result of a 'type' of participant, staff may wish to consider whether non-adherence actually reflects difficulties with conducting trial activities or concerns that adherence is harmful. Furthermore, loss to follow up or participant withdrawal from a trial may not be attributable to sociodemographic characteristics or a lack of interest in continuing participation. Rather, they may be the result of difficulties with adherence and/or participants' perception that their contribution is not worthwhile or is harmful. Careful and sensitive discussion regarding these aspects of participation may help to improve adherence and retention.

9.2.4 The benefits of personal contact for adherence and retention

Although gifts and newsletters are commonly used as retention tools and these were well thought of by LEAP parents, they did not report seeing them as necessary for their participation. Rather, it was the personal contact with staff that parents described as relevant to their continuing participation. Given this finding, and the finding of Williams et

al. (2008) that the profession of the staff member who is responsible for retention influences retention rates, it is perhaps time to consider whether, in the same way that trials now often have staff who are dedicated to recruiting participants, it would also be beneficial to employ staff who are dedicated to adherence and retention activities. Although this might incur a cost, the cost is likely to be offset against the improvements to adherence and retention rates, and thus against the utility of a trial's findings.

9.2.5 Understanding the influence of the wider social context

This study found that the wider social context in which a trial is recruiting participants has a substantial influence on the ease with which recruitment occurs and is also relevant to adherence and retention. Whilst LEAP staff found it relatively easy to enrol the required number of participants, in part, at least, due to the dearth of specialist allergy services, EAT staff found it more difficult because the design of the trial influenced a practice that was held in high regard by parents and HCP collaborators. A detailed assessment of the likely barriers, not just from the viewpoint of the participants, staff and the availability of trial resources, but also in terms of the social context in which the trial will be recruiting participants, would allow investigators to be forewarned of likely problems. Such knowledge would allow the resources and methods needed to overcome such barriers to be put in place prior to beginning recruitment.

In the following section I discuss the areas in which the study findings suggest that further research would be useful.

9.3 Further research

The findings of the study reveal three areas in which further research would help to illuminate participation in paediatric trials: understanding father's views; understanding

the views of those who decline participation; and exploring the best model for facilitating adherence and retention.

9.3.1 Understanding fathers' views

Whilst a few studies exploring parental views of their child's research participation have included both mothers and fathers (see for example Snowden et al. 2007; Shilling et al. 2011) and one study considered the views of fathers alone (Liaschenko and Underwood 2001), to date none appear to have compared the views of fathers and mothers. I interviewed ten fathers, a relatively substantial number in comparison to other studies. Data from fathers, mothers and LEAP and EAT staff suggest that fathers hold differing views regarding their child's research participation. The data also suggest that, although mothers are often the main point of contact when families are considering or have agreed to take part in research and fathers appear to play a less active role in participation, they are, nonetheless, very influential to the decisions that are made. Further research that explores fathers' perceptions of their children's research participation, and that compares these to the views of mothers would be beneficial. Such knowledge would help to promote recruitment processes that meet fathers' needs and might also improve trial recruitment, adherence and retention.

9.3.2 Understanding the views of those who decline participation

Although parents who chose not to enrol their children in EAT were interviewed for this study, they represented a particular group of parents, i.e. those who initially made contact with the staff but later declined participation. It was clear from online discussion forum data that some contributors would never have considered enrolling their children in research. In this study, therefore, two groups of parents who preferred not to enrol their children in EAT were identified: those who were willing to consider research

participation but were unwilling or unable to take part in EAT specifically and those who would not consider any research participation. Whilst gaining access to parents⁵⁹ who would not consider enrolling their children in any research may not be easy, studies that explore the views of these individuals are needed to help widen understanding of the reasons that parents decline trial participation.

9.3.3 Exploring the best method for facilitating adherence and retention

In LEAP and EAT adherence and retention was the role of all staff, although junior staff would often refer to senior staff if they thought it was necessary to negotiate aspects of the protocol with parents. Although this seemed to work well, having a specific recruiter role has been shown to be a more successful method of recruiting participants than approaches in which all staff are equally responsible for recruitment (Treweek et al. 2010). Given this, and the importance of personal contact for adherence and retention that this study found, it would be useful to objectively compare the relative merits of a model in which staff are employed primarily to facilitate trial adherence and retention, with an approach in which the funding for these posts is incorporated into the general staffing pool so that adherence and retention strategies are adequately resourced but are the responsibility of all staff.

9.4 Limitations

This study has several limitations. Firstly, rather than being embedded within LEAP and EAT, the study was an addendum to the trials. For this reason data regarding recruitment to both trials were collected retrospectively. Recruitment to LEAP had been completed before I started collecting data for this study. Furthermore, although EAT's recruitment was ongoing and I was able to observe recruitment conversations, data were collected

⁵⁹ Or adult participants or children themselves.

from parents themselves after they had made their decisions about whether or not to take part. I attempted to minimise recall bias with this group of parents by interviewing them as close to the time of the decision as possible (within 3-4 months), but inevitably their recollection of their choices around participation is likely to have been influenced by their further experiences within the trial (for those who agreed to take part) and by their ability to recall events that occurred sometime previously.

Studies exploring recruitment to paediatric trials have utilised tape recordings of the conversations that occurred between parents and staff and consider this to be an effective way of understanding the interaction, albeit one that is sometimes difficult to implement (Snowdon 2005; de Salis et al. 2008; Shilling et al. 2011). I did not take such an approach and although I carried out observation on the clinical trials unit where recruitment conversations were conducted, many of these initial conversations occurred on the telephone, as did a large proportion of the conversations relating to participants' ongoing participation. Whilst I could establish the gist of the parents' dialogue from the responses that staff gave and was able to ask staff for clarification of the parent's side of the conversation once the telephone call was complete, this method is less rigorous than the verbatim recording of both sides of the conversations.

Parents who were identified by LEAP staff as having 'problems' with participation did not receive an invitation to take part in the study. The reason that they gave for not allowing me to contact such parents was that they were concerned that the invitation may result in them withdrawing their children from LEAP. Although EAT staff did not restrict my contact with any parents, the exclusion of these LEAP parents may have resulted in a more positive account of parents' experiences in that trial than would otherwise have been the case. This may also have been compounded by the social desirability bias that is

inherent to interview data (Bowling 2002), although the observational data seemed to verify the predominantly positive experiences described by parents.

The number of parents who chose not to take part in the trials who were interviewed for this study was limited and those who were interviewed after choosing not to take part had made contact with the staff to express an initial interest in participating. As was evident in the data from online discussion forum conversations about potential participation in EAT another group of parents exist: those who would never consider enrolling their children in research. Although the online discussion forum data give a snapshot into the views of such parents, they lack the necessary depth to fully understand the views of this important group of parents. Similarly only three parents who withdrew their children from the trials were interviewed. This small number was, in part, due to the relatively small number of parents who had withdrawn their children from the trials at the time I was conducting the study. The inferences that may be drawn from the data gathered from such parents are clearly limited. Nonetheless they offer insights into the experiences of groups of parents who are traditionally hard to reach.

The generalisability of the data is also limited by the very specific nature of the trials that were used as case studies, and, perhaps more importantly, by the sociodemographic characteristics of participating parents. Most of the parents who I interviewed were educated to degree level or beyond, classified their ethnicity as White British, and lived in areas with low levels of deprivation; thus they are not representative of the general population of parents.⁶⁰ Despite this, within the sample of parents who I interviewed, I could find only one aspect of participation that was influenced by sociodemographic

⁶⁰ I could not access data regarding the representativeness of the parents who took part in this study in comparison to LEAP and EAT as a whole.

factors. As I have discussed previously, fathers sometimes held differing views about research participation than mothers.

As is conventional in studies that have been conducted using the principles of ethnography (Hammersley and Atkinson 1995), in the following section I reflect upon the use of the ethnographic method and the way that I, as the researcher, influenced data collection and analysis

9.5 Reflections on the method and reflexivity

This study is one of the few studies to have used ethnographic methods to explore research participation. By considering the views of parents and staff and by setting these within the context of the various fields within which parents and staff operated it was possible to gain a wide ranging view of recruitment, adherence and retention practices in LEAP and EAT. This was particularly the case when considering adherence and retention, two aspects of trial participation that, despite their potential to significantly influence a trial's outcome, have been under explored to date. For example, although staff and parents discussed the importance of the relationship they had developed during their interviews, the subtleties of this relationship were only apparent during the participant observation. Participant observation also allowed an understanding of the effort and approaches that staff put into facilitating all aspects of trial participation, the extent of which was not apparent in the interview data.

I reflected on my role in some detail in Chapter 4, highlighting how my previous knowledge of the trials and trials' staff had both advantages and disadvantages. My familiarity with the setting was useful in gaining access to the fieldwork setting and, in many cases, with building a rapport with the staff that promoted the collection of rich data. However, this familiarity is also likely to have had implications when collecting and

analysing the data. Early on in my fieldwork, when discussing my data with my supervisors, it became apparent that my knowledge of the setting led me to take aspects of practice for granted. After this recognition I tried to overcome this limitation by adopting a more questioning approach, looking more closely at the data and considering my own preconceptions. Continuing to discuss the data with my supervisors was also useful, however my familiarity with the setting will have had an influence on the gathering and analysis of data.

9.6 Conclusion

This appears to be the first study to have considered recruitment, adherence and retention within the same trials. The findings reveal that, rather than being three separate parts of participation, they are actually interrelated. Staff and parents considered adherence before children were recruited to the trials and those who were unlikely to be able to adhere either chose not to enrol or were advised against taking part. Motivations for enrolling in the trials were relevant for retention, particularly in terms of whether parents' expectations were met. Moreover, adherence and retention were closely linked; parents who found adherence difficult considered withdrawing from the trials whilst staff 'gave permission' for reduced adherence in order to promote retention.

This study is also one of few to explore participation in non-therapeutic trials and the findings reveal many similarities to and a few differences from therapeutic trials. Like those who took part in therapeutic trials, LEAP and EAT parents were also concerned about the risks of participation, but those who felt that their children would derive health benefits from taking part placed less emphasis on the risks of taking part. Similarly an unwillingness to accept randomisation presented a barrier for recruitment to LEAP and

EAT. Previous studies have found that parents often enrol their children in both therapeutic and non-therapeutic trials to access healthcare, and this study both corroborates and expands upon these findings. Whilst parents generally had several motivations for participation, when children were in need of healthcare and these needs could not be met via the standard healthcare route parents enrolled their children in the trials for predominantly 'selfish' reasons. Where parents had little need for the expertise that trial participation could afford them they discussed participation primarily in terms of helping others in society. However, unlike those who participated in therapeutic trials, parents did not generally find the decision difficult to make. Furthermore, rather than feeling overwhelmed or concerned about participation, for many LEAP and EAT parents participation offered hope.

The study findings highlight the importance of practical aspects of participation on recruitment, adherence and retention. As others have found (see for example van Stuijvenberg et al. 1998; Taylor and Kass 2001; Caldwell et al. 2002; Gattuso et al. 2006), parent and staff perceptions of the manageability of the trial activities were very important to all aspects of participation. However, this study illuminates previous studies findings. Rather than solely being concerned with the amount of time involved in the various visits and activities, a factor that one might presume to be important, whether parents felt that they and their children would or were contributing to the goals of the trial in a meaningful way played a significant role in participation. Discussing such concerns with staff often helped to alleviate parents' worries in this regard.

The study also reveals that LEAP and EAT staff had to balance their professional and personal responsibility to do their best by the participating children, their ethical duty not to coerce families into taking part or continuing to take part in the trials, and their

professional duty to ensure that the trials produced meaningful results. This finding is unlikely to be unique to paediatric trials. Other groups of individuals who are less able or unable to provide informed consent for participation are also labelled as 'vulnerable' within the context of research,⁶¹ and thus also subject to the same ethical guidelines regarding the benefits of participation. As their participation often requires that a relative or other representative provide proxy consent for their participation, the findings of this study may be applicable to, and thus useful to, those who conduct trials with vulnerable groups, regardless of their age.

Perhaps this study's key finding was the relevance of context. The interrelationship between the varying fields, particularly the fields of parenting and the trials, influenced all aspects of participation from initial recruitment decisions to facilitating adherence and minimising attrition from LEAP and EAT. Through the personal relationships that were built between staff and those who occupied the differing fields, staff were often, although not always, able to put strategies in place to try and reduce the gulf that existed between the various fields' philosophies. Concordance between the philosophies of parenting and trial fields was of particular importance, and the approaches that the staff took to facilitating trial participation reflected their understanding of this.

In developing an understanding of the approaches that staff took it has become evident that, whilst medical research is often thought of as cold, detached and inflexible (Lisdskog 2008; Moreira 2011) this is not always the case. As Paul, who worked for one of the trial funders and was thus somewhat removed from the day-to-day running of the trials remarked *'I'm guessing this whole thing's held together with human glue'* [Paul, Staff 16]. Reflecting both Titmuss' (1970) and Bourdieu's (1977) views of exchange, at least in the

⁶¹ Such as unconscious adults, or those with dementia or learning difficulties

context of LEAP and EAT, recruitment, adherence and retention were underpinned by reciprocity and negotiation which were dependent upon the relationships that developed between the staff and the participating families.

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Appendix 1: Participation in paediatric research review search terms

Database	Search terms			
	General	Recruitment	Adherence	Retention
SCOPUS	SUBJAREA (medi OR nurs OR psyc OR soci OR heal) AND TITLE (experience OR perception OR view* OR barrier OR attitude OR understanding OR account OR motivat* OR perspective OR reason OR factor OR concern) AND TITLE (trial OR research OR study) AND TITLE (parent OR mother OR father)	SUBJAREA (medi OR nurs OR psyc OR soci OR heal) AND TITLE (consent OR decision OR decide OR participat* OR participant OR choice OR choose OR permission OR willing*) AND TITLE (trial OR research OR study) AND TITLE (parent OR mother OR father)	SUBJAREA (medi OR nurs OR psyc OR soci OR heal) AND TITLE (adhere OR adherence OR adherent OR comply OR compliance OR compliant) AND TITLE (trial OR research OR study) AND TITLE (parent OR mother OR father)	SUBJAREA (medi OR nurs OR psyc OR soci OR heal) AND TITLE (retain OR retention OR LTFU OR follow) AND TITLE (trial OR research OR study) AND TITLE (parent OR mother OR father)
Cochrane database of reviews, clinical trials and methods studies		AB consent OR decision OR decide OR participat* OR participant OR choice OR choose OR permission OR willing*) AND AB (trial OR research OR study) AND AB (parent OR mother OR father)	AB (adhere OR adherence OR adherent OR comply OR compliance OR compliant) AND AB (trial OR research OR study) AND AB (parent OR mother OR father)	AB (retain OR retention OR LTFU OR follow) AND AB (trial OR research OR study) AND AB (parent OR mother OR father)

Appendix 2: Participation in prosocial healthcare activities review search terms

Database	Search terms		
	Blood donation	Organ donation	Research participation
SCOPUS	TITLE (experience OR perception OR view* OR barrier OR attitude OR understanding OR account OR motivat* OR perspective OR reason OR factor OR concern) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE ("blood donation" OR "blood donor")	TITLE (experience OR perception OR view* OR barrier OR attitude OR understanding OR account OR motivat* OR perspective OR reason OR factor OR concern) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE ("organ donation" OR "organ donor" OR "tissue donation" OR "tissue donor")	TITLE (experience OR perception OR view* OR barrier OR attitude OR understanding OR account OR motivat* OR perspective OR reason OR factor OR concern) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE (trial OR research OR study)
SCOPUS	KEY (ethic* OR altruis* OR pay* OR paid) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE ("blood donation" OR "blood donor")	KEY (ethic* OR altruis* OR pay* OR paid OR incentive*) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE ("organ donation" OR "organ donor" OR "tissue donation" OR "tissue donor")	KEY (ethic* OR altruis* OR pay* OR paid OR incentive*) AND SUBAREA (MEDI OR NURS OR HEAL OR PSYC OR SOCI) AND TITLE (trial OR research OR study)

Appendix 3: Narrative synthesis

Appendix 4: Ethical approval letter

Appendix 5: Research and Development approval letter

An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research: Staff Observation

(Parents in Research study)

You are being invited to take part in a study that is trying to learn more about the experiences of parents whose children take part in research. Before you decide whether to take part it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with other people if you wish. If anything is not clear or you would like more information please do not hesitate to contact us.

What is the purpose of the study?

The Parents in Research study aims to better understand the issues faced by parents whose children take part in research. We would also like to learn more about factors that influence parents when their children are taking part in experimental research. This study will help professionals to design research that is sympathetic to the needs of parents. It will also allow researchers to develop effective recruitment and retention strategies. This will help to improve future research and perhaps, therefore, the future healthcare of children.

Why have I been chosen?

You have been chosen because you are working with parents whose children are taking part in research.

Do I have to take part?

You do not have to take part in this study. Your decision to take part should be entirely voluntary. If you do decide to take part we will ask you to sign a consent form. After deciding to take part you are free to withdraw at any time without giving a reason. Deciding not to participate, or to withdraw from the study will not affect your employment.

What will happen to me if I take part?

This part of the study will involve one of the researchers observing what happens on the clinical trials unit. The researcher will be looking at how parents are given information to help them make decisions about their child's participation in the LEAP or EAT studies. If you agree to take part the researcher will include your daily work activities in her observations. The research should not interfere with the way that you work.

Will my taking part in the study be kept confidential?

The researcher will make some notes about the things that she observes on the unit. These notes will not include the names of any staff (or parents, children or other visitors). No one except the researcher and her supervisors will see these notes and these will be stored in a locked filing cabinet. Once the study is complete and the notes have been analysed they will be destroyed.

What will happen to the results of the study?

The results of this research will be summarised in a final report for a PhD (research training) and parts of this may be published in academic journals or presented at conferences. It will not be possible for anyone reading the final report, or listening to these presentations to identify you. If you would like to receive a copy of any published papers please let us know.

Who is organising and funding the study?

The Lead Investigator of the study is Helen Fisher. This study is being conducted for her PhD and she is being supervised by Dr Annette Boaz and Dr Christopher McKeivitt. All of these researchers work at King's College London. The study is being funded by a grant from the NIHR Biomedical Research Centre at Guys and St Thomas' NHS Foundation Trust and Kings College London.

Who has reviewed the study?

The study has been reviewed by the Kings College Hospital Research Ethics Proportionate review Sub-Committee and the Research and Development department and Guys and St Thomas' NHS Foundation Trust.

Contact details

Helen Fisher

Department of Health and Social Care,
Kings College London,
Guys Campus,
London, SE1 9RT

Tel: 020 7848 8732 or email: helen.r.fisher@kcl.ac.uk

What do I do if I want to take part?

If you would like to take part in the study or would like more information to help you decide please contact Helen via one of the means given above. Before the observation takes place she will ask you to sign the attached consent form.

Consent Form: Staff Observation

Title of Study: An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research.

Name of Lead Researcher: Helen Fisher

Name of Main Supervisor: Dr Annette Boaz

Initial Box

1. I have read and understood the information sheet (version **2** dated **17/12/09**) for the above study and have had the opportunity to ask questions.
2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving a reason.
3. I understand that all information will remain strictly confidential.
4. I agree that information collected about me as part of the study can be stored and analysed by the research team at Kings College London.
5. I agree to take part in the above study.

Name of participant

Signature

Date

_____	_____	_____
Name of researcher	Signature	Date

Participant Number: _____

Appendix 7: Parent invitation letter



University of London

Department of Health and Social Care Research
9th Floor Capital House
42 Weston Street
London
SE1 3QD

Tel: 0207 848 8732

helen.r.fisher@kcl.ac.uk

[insert date]

Dear Parent,

Parents in Research Study

I am conducting a study that hopes to learn more about the experiences of parents whose children take part in research. The study is part of my research training (PhD) and is being conducted at Kings College London. As your child is taking part in the [xxx] study I would be very interested in hearing from you. The attached three page information sheet contains some more details about the study and what your participation in it would involve.

The [xxx] study team have agreed to help us approach parents who may be interested in taking part in this research by sending out these letters. I will not tell anyone working on the [xxx] study whether you decide to participate, but the [xxx] study team will be able to read the final report once all of the information has been anonymised so that it is not possible to identify you or your child.

If you think you might like to take part or would like more information to help you decide, please do get in touch by phone email or letter. All my contact details are on the information sheet attached.

Thank-you for considering this study

Helen Fisher

Paediatric Nurse, NIHR Fellow

Appendix 8: Parent information sheet and consent form

An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research: Parent Interviews

(Parents in Research study)

You are being invited to take part in a study that is trying to learn more about the experiences of parents whose children take part in research. Before you chose whether to take part it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family, friends or your GP if you wish. If anything is not clear or you would like more information please do not hesitate to contact us.

What is the purpose of the study?

The Parents in Research study hopes to help professionals who carry out research with children to better understand the issues faced by parents whose children take part in research. We would also like to learn more about the choices that parents make about their child's participation. It is hoped that the knowledge we learn during this study will help professionals to design research that is sympathetic to the needs of parents. This may encourage more parents to agree to their child participating in research and might help lower the number of children who drop out of research. This would help future research studies produce useful findings that improve healthcare for children.

What will happen to me if I take part?

If you agree to participate you will be asked to take part in one interview which will last about an hour, although this will vary slightly depending on how much you want to tell us. The interview will take place at a time and place that is convenient to you, e.g. at your home. We would like to audiotape the interview so that the information you give can be accurately recorded. The main purpose of the interview is to understand your experiences of your child's participation in research and the choices that you make about your child's participation in the study.

After the interview we will give you the opportunity to see a typed version of the interview so that you can check we have accurately recorded the information you gave. Once all the interviews have been finished and we have looked at all the information, we hope to design a questionnaire that will be sent to a larger number of parents. This will allow us to gather a wide range of views. If you think you might like to help us design this questionnaire please tell the researcher.

Why have I been chosen?

You have been chosen because your child is or has participated in a research study (the LEAP or EAT study), or because you are thinking about enrolling your child in the EAT study.

Do I have to take part?

You do not have to take part in the Parents in Research study. Your decision about participating in this study will not affect your child's participation in the LEAP or EAT studies and should be entirely voluntary. If you do decide to take part we will ask you to sign a consent form. After deciding to take part you are free to withdraw at any time without giving a reason. Deciding to withdraw will not affect your child's participation in the LEAP or EAT studies, their or your standard medical care, or your legal rights.

Will my taking part in the study be kept confidential?

The information that you give us will be kept confidential. Only Helen will have access to the original tapes. When the interviews are typed up from the recordings, any identifying information (e.g. names) that has been used during the interviews will be removed.

Helen's supervisors will have access to the paper copies of the interviews but these will be anonymised. Although you were initially contacted by staff on the LEAP or EAT studies, none of the staff working on these studies will know whether you decided to take part in this research. LEAP and EAT study staff will be able to read the final report but this will not contain any information that allows you or your child to be identified.

Any information that is stored on a computer (e.g. the audio recordings) will be scrambled (encrypted) and locked with a password that is only to Helen. Names will not be written on any paper documents, and all paper documents will be kept in a locked

filing cabinet. All electronic and paper information will be carefully destroyed after the research has been completed.

What will happen to the results of the study?

It is likely that information from the interviews will be used to design a questionnaire. The questionnaire will use information from all of the interviews (we expect to conduct about 20 of these), and it will not be possible for anyone reading the questionnaire to identify you or your child.

The results of this research will be summarised in a final report which will form part of the research training (PhD) of one of the researchers. Parts of this report may be published in academic journals or presented at conferences. We will also write a summary of the findings for the parents of all children on the LEAP and EAT studies. It will not be possible for anyone reading the final report, or listening to these presentations to identify you or your child. If you would like us to send you a copy of the summary or any published papers, please let us know.

Who is organising and funding the study?

The lead researcher of the study is Helen Fisher. This study is being conducted as part of her research training (PhD) and she is being supervised by Dr Annette Boaz, Dr Christopher McKevitt and Professor Lack. All of these researchers work at Kings College London. The study is being funded by a grant from the NIHR Biomedical Research Centre at Guys and St Thomas' NHS Foundation Trust and Kings College London.

Who has reviewed the study?

The study has been reviewed by the Kings College Hospital Research Ethics Proportionate review Sub-Committee and the Research and Development department and Guys and St Thomas' NHS Foundation Trust.

Contact details

Department of Health and Social Care,
Kings College London,
Guys Campus,
London, SE1 9RT

Tel: 020 7848 8732 email: helen.r.fisher@kcl.ac.uk

What do I do if I want to take part?

If you would like to take part in the study or would like more information to help you decide please contact Helen by phone, email or letter (contact details above). She will then organise a convenient time and place for the interview. Before the interview takes place she will ask you to sign the attached consent form.

You may also like to visit the following websites which provide general information about taking part in research:

<http://www.healthtalkonline.org>

<http://www.peopleinresearch.org>

Consent Form: Parent Interview

Title of Study: An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research.

Name of Researcher: Helen Fisher

Name of Supervisor: Dr Annette Boaz

Initial

Box

6. I have read and understood the information sheet (version **3** dated **06/05/10**) for the above study and have had the opportunity to ask questions

7. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected. I understand that my child's research participation and medical care will not be affected by my decision to participate in this trial.

8. I understand that the interview will be tape recorded and that I can refuse to answer a question or ask for the interview to be terminated at any time.

9. I understand that all information will remain strictly confidential.

10. I agree that information collected about me as part of the study can be stored and analysed by the research team at Kings College London.

11. I agree that small parts of what I say may be quoted anonymously when the results of this research are reported.

12. I agree to take part in the above study.

_____	_____	_____
Name of participant	Signature	Date

_____	_____	_____
Name of researcher	Signature	Date

Participant Number: _____

Appendix 9: Parent interview topic guide

Introduction

Introduce the study and stress that the aim of this interview is to gain an understanding of:

- Sorts of reasons they decided to take part and how they came to their decisions
- How they have found research participation and the reasons they stay in the study

Stress confidentiality and anonymity issues. Remind parent they can terminate the interview at any time or choose not to answer a question.

Interview

- Which study is [your child] participating in?
- How long has [your child] been taking part?
- How old was [your child] when they were first enrolled?
- Which group is [your child] in?
- Some background questions?
 - Did you know much about research before you heard about the study?
 - Medical research or research in general?
 - What do you think about research in general?
 - (if parent works in research – why did they get into it?)
 - What are their occupations?
 - Have you heard much about research from the media?
 - Could you give examples of things you might have heard about and how this influenced your decisions regarding participation?
 - Do you know much about how research is regulated?
 - Is this something that you thought about before you started in the study?
 - Have you ever taken part in research before or known anyone who has?
 - Have you or anyone you known benefitted from research findings?
 - Do you think your views of research have changed since taking part?
 - Why do you think doctors and others conduct research?

- What was your child's general state of health when you had to make the decision?
 - Had you had much input from your doctor about eczema/allergy?
 - Which hcp's had you seen?
 - Were these NHS or private?
 - Did you feel able to cope with your child's health and or to access adequate healthcare when you heard about the study?
 - Did this influence your decision to participate?
 - If you had had better access to better doctors do you think you would have participated?

- Knowledge of food (peanut) allergy?
 - How much did you know about food (peanut) allergy before you heard about the trial?
 - Where did this knowledge come from?
 - Do you think you had a balanced view of what having allergies is like?
 - Was it something you had thought much about when you had (your child)?
 - Did you know anyone with food or other allergies?
 - How had this influenced their life and the lives of those around them?
 - How did your knowledge of food allergy or other allergies influence your decision to participate?

- How did you hear about the study?
 - What were your first thoughts when you heard about it?
 - Did anything worry you, was there anything that was particularly appealing?
 - What sorts of things did you do to get information about the study?
 - What sorts of things did you consider when making the decision?
 - Did you talk about the study with your partner?
 - Did you and your partner feel similarly positive/negative about the research participation or was one of you more positive than the other?

- If they disagreed how was this resolved?
 - If you had to convince them then why bother?
 - Did you get advice from anywhere else? (e.g. GP, health visitor, friends, family, support groups, the internet)
 - How long did you take to decide and how long did the study team give you to make a decision – was there any urgency?
 - How do you think making this choice for your child compares with if you had been making for yourself or an older child?
 - Was your decision influenced by any cultural or religious guidance? Could you tell me a little bit about this?
 - How did you come to your final decision?
 - What was the one main reason you chose to participate?
 - Did you think about the fact that the trial would carry on for quite a long time?
 - How did this influence your decision to participate?
 - Have you told friends/family about your participation in LEAP?
 - What have their reactions been?
 - How has this influenced your research participation/made you feel?
 - If negative reactions how do these people differ from you?
- Did you hope to achieve anything by taking part?
 - Did you think you might get anything out of participating?
 - What sorts of things did you think you might get.
 - How important was it to you that there was a benefit to taking part?
 - Were the benefits of participation considered by you only or did the study staff discuss potential benefits before you signed up?
 - What sorts of benefits did they describe?
 - Were downsides something that you had considered and if so what sorts of things did you think about?
 - Did the staff also talk about the downsides?
 - Have there been benefits to participation?
 - What have these been?

- (If you didn't get feedback would you still participate?)
 - Have there been downsides to participation? What have these been
 - Have these benefits/downsides occurred throughout your time participating or have they been more at one time or another?
 - How important to you was it that the study was exploring prevention of peanut allergy?
 - Did it influence your decision to participate?
 - How important is it now?
 - Does it influence it now?
 - Did you think about the fact that you would be influencing public policy before you signed up?
 - How did this influence your decision to participate?
 - Do you think about it now? Does it influence your continuing participation?
- How has your child's participation in the research been so far?
 - Did you have a strong opinion as to which group you wanted to be randomised to?
 - Did you end up in this group?
 - If you didn't get the group you wanted/hadn't have got the group you'd wanted how did this make you feel?
 - Did the study staff know your preference and how did they handle you not getting it?
 - Is there anything else you would have liked them to have done?
 - How have you found doing the things you have been asked to do and attending the visits?
 - Did your child eat (the foods) easily/Has it been easy to avoid (the foods)?
 - If not how has this made you feel/what have you done about it?
 - How diligently do you monitor consumption/avoidance? How does this compare to your general monitoring of their diet and/or to that of their siblings (Also relate to food allergy)?

- If the child goes to a friends house/nursery/school do you tell them that they are taking part in the study?
- What sorts of things do you say?
- If you don't tell them why is this?
- If your child misses (the foods)/has accidentally had some how do you feel about it?
- How does this compare with your feeling about missing medications e.g. antibiotics if they have ever been prescribed?
- Have there been situations where you have not been able to do what was expected of you by the research team?
- Could you describe any of these times and tell me what you did?
- Have you or your partner been tempted not to tell the truth about consumption/avoidance?
- Could you give me an example of this and tell me what you did about it?
- Have the study staff ever talked about the need for honesty or acknowledged that sometimes avoidance/consumption won't be possible?
- Have you attended the follow up visits for the trial/completed the diaries that have been sent?
- How have these visits/diaries been?
- Have you been tempted not to attend/complete the diaries?
- Has the research team helped you to adhere to avoiding/consumption and attending visits etc?
- Could you give me examples of how they have helped or things you would have liked them to have done?
- Does the study impact much on your life?
- Is this something that you considered before you enrolled? Was the 'impact factor' important when you signed up?
- Has it met your expectations in terms of impact on your life? How important is it now? Is this different to when you signed up?

- **Withdrawing**
 - Have there been times when you have considered withdrawing from the trial? Could you describe this and tell me who /where you got advice from?
 - If not then why do you think this is?
 - Could you tell me why you have decided to stay in the trial?
 - Is the reason you have stayed in the trial the same as the reason you initially decided to take part?
 - If not how does this differ and why do you think your reasons have changed?
 - Does the team do anything to promote retention to the study?
 - Is there anything that you think they should do that they don't?
 - Do you think much about the fact you are taking part in research?
 - What things make you think about it?

If have mentioned a 'help out' attitude ask where this comes from – home, school, culture, religion etc.

- Would you consider enrolling your child (or another child) in other research?
 - Would you recommend taking part in research to a friend with a child?
 - Why did you decide to take part in my study?
 - Is there anything else that you feel we should know?
 - Any questions?

Parents in Research Study: Demographic questionnaire for parents who participate in interviews

We would like to gather a little information about you:

Please tick as appropriate:

1. Are you the child's?

Mother	<input type="checkbox"/>	Father	<input type="checkbox"/>	Other (pl state) _____
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2. Which age group do you belong to?

16-20 years	<input type="checkbox"/>	21-30 years	<input type="checkbox"/>	Other	<input type="checkbox"/>
31-40 years	<input type="checkbox"/>	41-50 years	<input type="checkbox"/>		
51-60 years	<input type="checkbox"/>	51-60 years	<input type="checkbox"/>		

3. What is your highest level of education?

Basic secondary/high school (e.g. GCSE)	<input type="checkbox"/>	Advanced secondary (e.g. A levels)	<input type="checkbox"/>
Diploma	<input type="checkbox"/>	First Degree (e.g. BSc)	<input type="checkbox"/>
Further Degree (MSc, PhD)	<input type="checkbox"/>	Other (pl state) _____	

4. How would you describe your ethnicity? (please tick one)

A. White British	<input type="checkbox"/>	Irish	<input type="checkbox"/>
Other	<input type="checkbox"/>		
B. Mixed White and Black Caribbean	<input type="checkbox"/>	White and Black African	<input type="checkbox"/>
White and Asian	<input type="checkbox"/>	Other Mixed	<input type="checkbox"/>
C. Asian Indian	<input type="checkbox"/>	Pakistani	<input type="checkbox"/>
Bangladeshi	<input type="checkbox"/>	Other Asian	<input type="checkbox"/>
D. Black Black British	<input type="checkbox"/>	Black Caribbean	<input type="checkbox"/>
Black African	<input type="checkbox"/>	Black Other	<input type="checkbox"/>
E. Chinese/OtherChinese	<input type="checkbox"/>	Other Ethnic Group	<input type="checkbox"/>
(please state) _____			

Appendix 11: Staff interview participant information sheet and consent form

An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research: Staff Interviews

(Parents in Research study)

You are being invited to take part in a study that is trying to learn more about the experiences of parents whose children take part in research. Before you choose whether to take part it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with other people if you wish. If anything is not clear or you would like more information please do not hesitate to contact us.

What is the purpose of the study?

The Parents in Research study aims to better understand the issues faced by parents whose children take part in research. We would also like to learn more about factors that influence parents when their children are taking part in experimental research. This study will help professionals to design research that is sympathetic to the needs of parents. It will also allow researchers to develop effective recruitment and retention strategies. This will help to improve the quality of future research and perhaps, therefore, the future healthcare of children.

What will happen to me if I take part?

If you agree to participate you will be asked to take part in one interview. The length of the interview will vary according to your answers but should take about an hour. The interview will take place at a time and place that is convenient to you. We would like to audiotape the interview so that the information you give can be accurately recorded. The main purpose of the interview is to get your views on the reasons parents participate in

research. After the interview we will give you the opportunity to see a typed version of the answers you gave so that you can check that we have accurately recorded your views.

Why have I been chosen?

You have been chosen because you are working with parents who enrol their children in experimental research. We believe that this gives you a unique insight into the issues faced by these parents.

Do I have to take part?

You do not have to take part in this study. Your decision to take part should be entirely voluntary. If you do decide to take part we will ask you to sign a consent form. After deciding to take part you are free to withdraw at any time without giving a reason. Deciding not to participate, or to withdraw will not affect your employment.

Will my taking part in the study be kept confidential?

Nothing that you say will be read by anyone apart from the staff who are involved in the Parents in Research study. Names will not be written on any of the recordings or transcripts. All electronic information will be encrypted (scrambled) and kept on a computer that is locked with a password known only to the researcher. All paper information will be kept in a locked filing cabinet. All paper and electronic information will be carefully destroyed after the research has been completed.

What will happen to the results of the study?

It is likely that information from the interviews will be used to design a questionnaire. The questionnaire will use information from all staff and parent interviews (we expect to conduct about 30 of these), and it will not be possible for anyone reading the questionnaire to identify you.

The results of this research will be summarised in a final report which will be submitted as part of a PhD (research training). Parts of this thesis will be published in academic journals or presented at conferences. It will not be possible for anyone reading the final report, or listening to these presentations to identify you. If you would like us to send you a copy of any published papers please let us know.

Who is organising and funding the study?

The lead researcher of the study is Helen Fisher. This study is being conducted for her PhD and she is being supervised by Dr Annette Boaz and Dr Christopher McKeivitt. All of these researchers work at Kings College London. The study is being funded by a grant from the NIHR Biomedical Research Centre at Guys and St Thomas' NHS Foundation Trust and Kings College London.

Who has reviewed the study?

The study has been reviewed by the Kings College Hospital Research Ethics Proportionate Review Sub-Committee and the Research and Development department and Guys and St Thomas' NHS Foundation Trust.

Contact details

Department of Health and Social Care,
Kings College London,
Guys Campus,
London, SE1 9RT

Tel: 020 7848 8732 email: helen.r.fisher@kcl.ac.uk

What do I do if I want to take part?

If you would like to take part in the study or would like more information to help you decide please contact Helen by email, phone or letter. She will then organise a convenient time and place for the interview. Before the interview takes place she will ask you to sign the attached consent form.

Consent Form: Staff Interview

Title of Study: An exploration of factors that influence research participation by parents who are invited to enrol their children in longitudinal experimental research.

Name of Researcher: Helen Fisher

Name of supervisor: Dr Annette Boaz

Initial

Box

13. I have read and understood the information sheet (version **2** dated **17/12/09**) for the above study and have had the opportunity to ask questions.

14. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving a reason.

15. I understand that the interview will be tape recorded and that I can refuse to answer a question or ask for the interview to be terminated at any time.

16. I understand that all information will remain strictly confidential.

17. I agree that information collected about me as part of the study can be stored and analysed by the research team at Kings College London.

18. I agree that small parts of what I say may be quoted anonymously when the results of this research are reported.

19. I agree to take part in the above study.

_____	_____	_____
Name of participant	Signature	Date

_____	_____	_____
Name of researcher	Signature	Date

Participant Number: _____

Appendix 12: Staff interview topic guide

Introduction

Introduce myself and thank the staff member for participating in the study. Ask how they would like to be addressed.

Introduce the study and stress that the aim of this interview is to gain an understanding of:

- the issues that staff think parents face when their child is participating in experimental research.
- The ways in which staff help parents to make choices about their child's participation in experimental research.

Stress confidentiality and anonymity issues. Remind staff member they can terminate the interview at any time.

Interview

- What is your role and how long have you been with the team?
 - How long had the research been going on when you started with the team?
 - What did you think about the research when you first heard about it?
 - How did you come to join the team?
 - Have you any other experience of working with parents whose children are taking part in research? How is this the same/different?
 - Have you or anyone you know ever taken part in research? Do you know anyone (other than your patients) who has taken part in research?
 - Before you joined the research team did you think much about research?

FOR THOSE INVOLVED IN PROTOCOL DEVELOPMENT

- How much time was spent planning the protocol?
 - Who was involved in the protocol development? What was each of their roles?
Do you think the inclusion of any other roles would have been useful?

- Were there any lay people involved in the research planning? What contribution did they make?
- How much time was devoted during the planning phase to issues regarding recruitment, adherence and retention?
- Do you think this was sufficient – if not why not?
- Did the planning team generally agree about recruitment and retention strategies? If not what sorts of differences existed and how were these resolved?
- Overall were you happy with the recruitment, adherence and retention strategies that were included in the protocol? If not what else would you have liked to have seen and why was this not included?
- Has it been necessary to amend the recruitment, retention and adherence strategies since you started the trial? If yes why was this necessary and what has changed? Have the changes worked? How were the changes planned, implemented and agreed?

FOR ALL STAFF (WHERE APPROPRIATE)

- Could you tell me a little bit about how parents are/were recruited to the trial?
 - How easy/hard was it to recruit parents?
 - What strategies were put in place to aid recruitment?
 - Do you think enough was done or should other strategies have been tried? (If other strategies should have been tried why were they not implemented?)
 - Which of the strategies were particularly useful/ did not work?
 - What do you think parents feel when they are first invited to enrol their children in research?
 - Why do you think the parents in this study decided to take part?
 - What were the main reasons for parents refusing to take part?
 - Do you think the reasons are typical of all research or was there anything specific about this research that is particularly appealing/ unappealing?
 - Do you think anything could/should have been done to change this?

- Where did parents get information to help them decide whether to take part?
Do you think there were any sources of information that were particularly useful to parents or that swayed them in a particular direction?
- Were there differences in the sorts of parents who decided to take part and those who decided not to (e.g. mums and dads, ages of parents, socioeconomic status, parents with older siblings)?
- What sorts of outside influences do you think have an influence on parents' choices about participation (e.g. media, other healthcare professionals)? Could you give me any examples of a time when one of these outside influences has been apparent?
- Could you tell me about how parents are helped to comply with the research procedures?
 - Could you tell me what is done generally and also about how you personally help parents to comply?
 - Are most parents managing to comply? Could you give me examples of the sorts of problems that parents have in complying? Do you think one group finds it harder than the other to comply? Is this the same throughout the study or do you think it changes with time?
 - What happens when parents do not comply with the protocol? Could you give me an example of a situation where a parent hasn't complied and tell me what has been done about it?
 - Does everyone in the team do similar things to help compliance or are there differences? Could you give me an example of any differences regarding the promotion of compliance and how these are resolved?
 - What is the general feeling in the team when a parent does not comply?
 - What aspects of the protocol do you think parents find it hard/easy to comply with? Has anything been done to help with the harder bits of the protocol? Do you think that more should be done and if so what sorts of things would be useful? Why have these not been implemented?
 - Do you think that there are any issues regarding compliance that are specific to this study compared with other clinical trials, for example drug trials?

- Roughly how many parents have withdrawn from the study?
 - Has this been more or less than you/the team had anticipated?
 - What reasons did the parents give for withdrawing?
 - If the team gets/got the impression that a parent would withdraw what is/was done about it? Could you give me examples of a time when a parent withdrew and a time when a parent who thought about withdrawing was kept in the study?
 - Have there been many parents who been lost to follow up/lost to follow up but then found again?
 - What measures have been taken prevent LTFU or to 'track down' parents who were thought to be lost to follow up?
 - If you have managed to track parents down, have you managed to subsequently keep them in the study? How have you managed to do this, and what were the reasons they were 'nearly LTFU.' Could you give me an example of such a situation?
 - How do you think parents can be encouraged to remain within the trial until its conclusion?
 - What strategies have been put in place to encourage retention of parents and what strategies do you personally use? Are there any strategies that you think should be implemented that have not been? What are the reasons for this?

- Is there anything else that you feel we should know?
- Do you have any questions for us?

Appendix 13: Primary documents for documentary analysis

EAT Primary documents

- Standard introduction 'Best for Baby' booklet
- Early introduction 'Baby's First' booklet
- Summary of events for food challenge
- 3 month general questionnaire
- Health and diet questionnaire
- Maternal diet questionnaire; pregnancy and breastfeeding
- Parent information sheet
- EAT study website www.eatstudy.co.uk accessed on 2/2/11 and 18/5/11
- Early introduction group follow on tips and recipes
- Eating well for 1-5 year olds
- EAT study 1 page parent information sheet
- Five day food diary
- Weekly diary
- Monthly diary
- EAT recruitment flyer

LEAP Primary Documents

- Patient summary letter for GP
- Treatment plans for children with allergic reactions
- Child travel plan detailing the need for allergic children to carry emergency medications in hand luggage of aeroplanes
- Expenses claim form
- Three day food diary

- Peanut recipes
- LEAP peanut recipes
- LEAP peanut consumption advice
- LEAP peanut avoidance advice
- LEAP egg avoidance tips
- List of peanut and peanut protein containing products
- Letter regarding Israel study (18/11/08)
- LEAP stories newsletters, Issues: 1 (May 2008), 2 (June 2009), 3 (February 2010), 4 (January 2011)
- Season's greetings cards 2007, 2008, 2009, 2010
- Appointment card
- Call centre script for recruitment
- LEAP recruitment flyer
- LEAP egg allergy recruitment poster
- LEAP eczema recruitment poster
- LEAP study website www.leapstudy.co.uk accessed on 09/03/11

Appendix 14: Secondary documents for documentary analysis

Online discussion forums considering EAT participation

- http://www.mumsnet.com/Talk/breast_and_bottle_feeding/908385-EAT-Study-WWYD/AllOnOnePage last accessed 18/06/11
- http://community.babycentre.co.uk/post/a4580805/eat_study_early_weaning_of_allergenic_foods?cpg=5&csi=2015488821&pd=4 last accessed 26/06/11

Media activity

Newspapers/magazines with articles advertising EAT

- Over weaning? The Times 18th January 2011.

Newspapers/magazines with articles advertising LEAP

- Peanut allergy, a hard nut to crack? Norwegian article in Allergi: PrakXsis
- Hands up who wants peanuts for tea? Observer food monthly Sunday 24th June 2007
- Chiswick toddler fights life threatening peanut allergy. Richmond Twickenham times Tuesday 3rd July 2007
- Peanut study could help thousands. Herald Scotland 28th July 2007
- Peacocks Leap to aid allergy study. Wandsworth Times 2007
- Eczema babies sought for ground breaking research. Southwark news article 2007
- 'I thought my child might die'. Jewish Chronicle 15th December 2006
- Fear and Allergies in the lunchroom. Newsweek November 5th 2007

- To head off allergies, expose your kids to pets and dirt early. Really. USA today 22/03/2006
- Dining with death. New Scientist June 2006
- Peanut allergy – the facts. Act against allergy newsletter 2006
- Peanut study challenges government thinking. Anaphylaxis campaign 2006
- Learning Early about Peanut Allergy, BSACI article 2006
- Study LEAPs to the aid of child peanut allergy sufferers. Dietetics today March 2007
- Getting away to a good start. Independent community pharmacist. January 2008.
- Making the LEAP between eczema and peanut allergy. National Eczema Society 2006.
- Allergies. Pregnancy Baby and you. Special Report. October 2008.
- Food allergy. Whole Health Journal. Spring 2006
- The paediatric allergy team. Foods matter. February 2007

Online articles advertising LEAP

- Peanut allergy study seeks babies BBC 3rd May 2007
<http://news.bbc.co.uk/1/hi/health/6618865.stm> accessed 09/03/11
- New research into peanut allergy BBC 2nd May 2007
<http://news.bbc.co.uk/1/hi/programmes/breakfast/6617019.stm> accessed 09/03/11

Appendix 15: Tertiary documents for documentary analysis

Food allergy related

- Crunch time for peanut allergies. <http://www.independent.co.uk/life-style/health-and-families/features/crunch-time-for-peanut-allergies-885074.html> accessed 09/03/11
- Early peanut exposure may reduce chances of allergy: study. <http://www.foodnavigator.com/content/view/print/226100> accessed 09/03/11
- British study on peanut allergies, a leap of faith. <http://smilinggreenmom.com/2010/03> accessed 09/03/11
- Prevention or avoidance? Study into infant peanut allergy. BSACI, Press release.
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Review of Advice on Peanut Avoidance
- Is our nut allergy advice nutty? http://www.timesonline.co.uk/tol/life_and_style/health/features/article5246192 accessed 09/03/11
- Study examines peanut allergies in England <http://www.nhs.uk/news/2011/02February/Pages/peanut-allergies-in-England.aspx> accessed 08/02/11
- Hope over peanut allergy cure <http://news.bbc.co.uk/1/hi/health/7899383.stm> accessed 09/03/11
- Doctors launch major trials to treat childhood peanut allergy after promising pilot study <http://www.guardian.co.uk/science/2010/feb/21/peanut-allergy-clinical-trial> accessed 08/04/10

- Children with allergies 'being let down' <http://www.bbc.co.uk/news/health-11494534> accessed 28/11/10
- The rise and rise of allergies <http://www.bbc.co.uk/news/health-12550300> accessed 23/02/11
- Alternative allergy test offers 'mislead parents' <http://www.bbc.co.uk/news/health-12531063> accessed 23/02/11
- Food allergy in children and young people. NICE guideline. <http://publications.nice.org.uk/food-allergy-in-children-and-young-people-cg116> accessed 03/03/11

Infant feeding related

- Cave, S. and Fertleman, C. (2007) *Your baby week by week*. Chatham, Vermillion. [used by Jeanette [E35MD] when deciding whether to take part in EAT]
- Mums who choose bottle over breastfeeding 'demonised' <http://www.bbc.co.uk/news/health-12008913> accessed 12/02/11
- How should mothers feed their new babies?: Your comments <http://www.bbc.co.uk/news/health-12020343> accessed 18/12/10
- Weaning before six months 'may help breastfed babies' <http://www.bbc.co.uk/news/health-12180052> accessed 17/01/11
- Children 'missing out on research benefits': scrubbing up series <http://www.bbc.co.uk/news/10373714> accessed 08/07/10
- Department of Health (2009) *Birth to Five*. London, COI.
- Baby led weaning website <http://www.rapleyweaning.com/> accessed 18/05/11

- NHS (2007) Weaning: Starting solid food, DoH, London.
- Exclusive BF for 6 months may be harmful
http://www.mumsnet.com/Talk/in_the_news/1125016-Exclusive-BF-for-6-months-may-be-harmful/AllOnOnePage accessed 18/05/11

Research related

- The academy of medical science. A new pathway for the regulation and governance of health research. January 2011.
- Should patients be obliged to take part in research?
<http://news.bbc.co.uk/1/hi/health/8399763.stm> accessed 21/01/11
- When ethics committees kill. <http://www.badsience.net/2011/03/when-ethics-committeees-kill> accessed 31/03/11
- Light drinking no risk to baby, say researchers.
<http://www.bbc.co.uk/news/health-11476456> accessed 17/06/11
- Funding shortfall puts cystic fibrosis research on hold.
<http://www.bbc.co.uk/news/health-13643267?print=true> accessed 06/06/11
- General Medical Council (2010) Dr Andrew Jeremy Wakefield: Determination on serious professional misconduct and sanction.
http://www.gmcuk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf
 accessed 10/03/12
- MMR row doctor Andrew Wakefield struck off register.
<http://www.guardian.co.uk/society/2010/may/24/mmr-doctor-andrew-wakefield-struck-off> accessed 01/06/10

- Andrew Wakefield found 'irresponsible' by GMC over MMR vaccine scare.
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accessed 14/03/10
- Cooksey, D. (2006) *A review of UK health research funding*. Norwich, HMSO.
- Department of Health. (2005) *Research governance framework for health and social care*. 2nd Edition. London, COI.
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- World Medical Association. (2008) *Declaration of Helsinki*. 8th amendment. World Medical Association.

Appendix 16: Details of parents who participated in the study

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Lily	L1MC	27	31-40	First degree	Chinese	Yes	Severe reaction to egg	Not known	Not known
Jemima	L2M1	31	31-40	Further degree	White British	Yes	Reaction to egg	Lawyer	Not known
Yvonne	L3MC	23	41-50	Further degree	White British	No	Poorly controlled eczema	Researcher	Not known
Colette	L4MC	41	31-40	Advanced secondary	White British	No	Reacted to milk and egg quite badly	Personal assistant	Not known
Hazel	L5MC	42	31-40	Further degree	White French	No	No problems	Not known	Not known
Alison	L6M1	41	31-40	First degree	White British	Yes	Suspected allergies and bad eczema	Accountant/ housewife	Banker
Mercy	L7MC	20	41-50	Diploma	Black African	No	Asthma	Caterer	Not known
David	L8F1	24	31-40	First degree	White British	No	Bad eczema and possible milk allergy	Hairdresser	Postman
Sally	L9M1	24	31-40	First degree	White British	No	Egg allergy	Lawyer	Trader

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Karen	L10MC	16	31-40	First degree	White British	No	Multiple food allergies, eczema and asthma	Teacher	Accountant
Sharon	L11MC	36	31-40	Diploma	White British	yes	Multiple food allergies, eczema and asthma	Stock controller	Lorry driver
Francesca	L12MI	29	41-50	First degree	White Brazilian	No	Bad eczema and several food allergies	Administrator	University night worker
Amy	L13MI	33	31-40	First degree	White British	No	Eczema and egg allergy	Management consultant	Energy assessor
Holly	L14MC	24	21-30	Diploma	White British	No	Eczema	Nurse	Telecom worker
Keira	L15MC	27	31-40	First degree	Black British	No	Eczema and milk allergy	Carer	Not known
Mark	L16FI	36	31-40	Diploma	White British	No	Egg allergy	Housewife	Environmental officer
Xanthe	L17MI	22	41-50	Further degree	White British	No	Egg and milk allergy	Administrator	Not known
Trina	L18MI	38	31-40	First degree	White British	No	No problems	Solicitor	Not known

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Charles	L19FC	20	31-40	Further degree	White French	Yes	Eczema	Lawyer	Web designer
Lizzie & Kevin	L20MI & L21FI	18	21-30	First degree	White British	No	Eczema	Teacher	Teacher
			31-40	First degree	White British	Yes			
Ada	L22MC	36	31-40	First degree	Black African	No	Eczema and egg allergy	Solicitor	Postman
Joanna	L23MC	25	31-40	First degree	White British	No	Eczema	Teacher	Works in IT
Nicole	L24MI	24	31-40	First degree	White British	No	Eczema	Lawyer/ housewife	Golf professional
Michaela	L25MI	42	31-40	Further degree	White African/ German	Yes	Eczema and egg allergy	Psychologist	Psychologist
Bea	L26MC & E56MI	38 & 1	31-40	First degree	White Other	No	Eczema & no concerns	Communication officer in NHS	Works in advertising
Roy	L27FC	29	41-50	First degree	White British	No	Eczema	Works in marketing	Works in marketing

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Brigitte	L28MIW	4 (duration in trial, 2+ years since withdrew)	31-40	Further degree	White Polish	No	Eczema	Financial management	Builder
Janine	L29MI	40	31-40	Further degree	White Latin American	Yes	Eczema and multiple food allergies	Paediatrician	Works in finance
Maeve	L30MC	37	31-40	Advanced secondary	Black Somaliian	Yes	Eczema	Researcher	Not known
Neil	L31FC	42	41-50	Advanced secondary	White Scottish	No	Eczema	Theatre organiser	Student
Eve	E32MD	3 (since declined participation)	31-40	Further degree	White British	No	No concerns	NHS administrator	Medical student
Andrea	E33MD	4 (since declined participation)	31-40	Further degree	White British	No	No concerns	Lawyer	Economist
Lesley	E34MIW	3 (duration in trial, 1yr since withdrew)	31-40	First degree	White British	No	No concerns	Teacher	Not known
Jeanette	E35MD	2 (since declined participation)	31-40	First degree	White British	No	No concerns	Management	Computer programmer
Georgie & Gareth	E36MD & E37FD	2 (since declined participation)	31-40	Basic secondary	White British	No	No concerns	Fulltime mother	Driver
			31-40	Basic secondary	White British	No			

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Pippa	E38MD	3 (since declined participation)	31-40	First degree	White British	Yes	No concerns	Project development	Engineer
Lyndsey	E39MI	1	21-30	Further degree	White British	Yes	No concerns	Teacher	London Underground ticket officer
Rebecca	E40MI	1	31-40	Further degree	White British	Yes	No concerns	Works in marketing	Not known
Christina	E41MC	4	21-30	Advanced secondary	White British	No	No concerns	Student	Student
Marianne & Andrew	E42MC & E43FC	2	31-40	First degree	White British	No	No concerns	Housewife/ teacher	RAF pilot
			31-40	First degree	White British				
Alice	E44MI	3	21-30	First degree	White British	Yes	No concerns	Child minder/ research assistant	Estates manager
Naomi	E45MI	4	31-40	First degree	White British	Yes	No concerns	Charity worker	Works in printing
Jess	E46MI	3	21-30	Advanced secondary	White British	No	No concerns	Student	Computer programmer

Interviewee	Interview number	Duration in trial (months)	Age group	Educational level	Ethnicity	Previous research participation	Health of child before participation	Mother's profession	Father's profession
Lorna	E47MI	4	21-30	First degree	White British	No	No concerns	English teacher	Science teacher
Natasha & Ralph	E48MC & E49FC	4	21-30	First degree	White British	No	No concerns	Personal assistant	Golf course builder
			31-40	Diploma	White British	No			
Talia	E50 MD	6 (since declined participation)	41-50	First degree	White British	No	No concerns	Pharmacist	Builder
Vicky	E51MIW	3 (duration in trial, 2+ years since withdrew)	31-40	First degree	White British	No	No concerns	Accountant	IT analyst
Isla	E52MI	3	31-40	First degree	White British	Yes	No concerns	Teacher	Teacher
Sophie	E53MI	2	31-40	First degree	White British	No	No concerns	Accountant	IT analyst
Rosie & Tom	E54MI & E55FI	2	31-40	Further degree	White British	No	No concerns	Teacher	Works in agriculture
			31-40	Further degree	White British	No			
			31-40	Further degree	White British	No			